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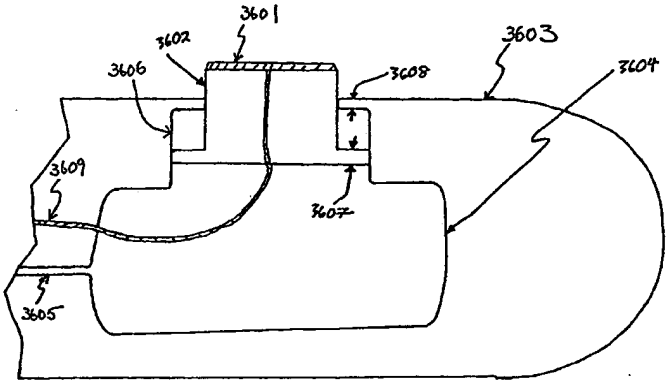

(57) Abstract

This invention is a device and procedure for the correction of optical abnormalities in a human eye. It involves use of an inventive electrosurgical energy probe with specific physical configurations. The process preferably utilizes a high frequency RF electrodesiccation or ablation device. The procedure involves the initial step of forming at least one access site allowing access to the corneal volume behind the Bowman's Layer. It preferably is placed in the anterior surface of the cornea through and ending posterior to the Bowman's layer of the eye. The electrosurgical probe is then introduced into the access site and, depending upon the visual abnormality to be corrected, the probe is activated to adjust the volume of the corneal stromal layers through ablation or desiccation. The shape of the volume desiccated or ablated is dependent upon the aberration to be corrected. The depth of tissue ablated may be adjusted by varying the height of the electrically active site of the electrosurgical probe. The height can be varied by raising or lowering a piston (3602) supporting the active site. The piston (3602) can be raised or lowered either pneumatically, or by attachment to an electrically controlled thermal expansion element which raises and lowers the piston as the thermal expansion element expands and contracts. Alternatively, the active site can be located on a balloon–type material which is pneumatically inflated to alter the height of the active sight above the nonconductive portion of the electrosurgical probe.

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CORNEAL ELECTROSURGICAL PROBE WITH A VARIABLE-HEIGHT ACTIVE SITE

Field of the Invention

The field of invention relates to a procedure for the correction of optical abnormalities in a human eye. More specifically, the field of the invention relates to use of an electrosurgical energy probe which may be of a specific physical configuration as outlined below. This invention also includes suitable electrodes for performing the noted process. The process preferably utilizes a high frequency RF electro-desiccation or ablation device. The procedure involves the initial step of forming at least one access site allowing access to the corneal volume behind the Bowman's layer. It (the access site) preferably is placed in the anterior surface of the cornea through and ending posterior to the Bowman's layer of the eye. The electrosurgical probe is then introduced into the access site and, depending upon the visual abnormality to be corrected, the probe is activated to adjust the volume of the corneal stromal layers through ablation or desiccation. The shape of the volume desiccated or ablated is dependent upon the aberration to be corrected. For instance, if the optical aberration to be alleviated is hyperopia, a circular corneal volume reduction taking place about the outer periphery of the corneal mass may be accomplished. In other instances, such as for the treatment of astigmatism, certain smaller sections of the peripheral corneal volume may be shrunk. In certain circumstances, Bowman's layer may be cut to allow the curvature of the cornea to change after the corneal volume adjustment. These relief cuts may be radial, circular, semicircular or any other form appropriate for the optical adjustment needed.

Background of the Invention

Anomalies in the overall shape of the eye can cause visual disorders. Hyperopia ("farsightedness") occurs when the front-to-back distance in the eyeball is too short. In such a case, parallel rays originating greater than 20 feet from the eye focus behind the retina. In contrast, when the front-to-back distance of eyeball is too long, myopia ("nearsightedness") occurs and the focus of parallel rays entering the eye occurs in front of the retina. Astigmatism is a condition which occurs when the parallel rays of light do not focus to a single point within the eye, but rather have a variable focus due to the fact

that the cornea refracts light in a different meridian at different distances. Some degree of astigmatism is normal, but where it is pronounced, the astigmatism must be corrected.

Hyperopia, myopia, and astigmatism are usually corrected by glasses or contact lenses. Another method for correcting those disorders is through the implantation of polymeric rings (intrastromal corneal rings or "ICR's") in the eye's corneal stroma to change the curvature of the cornea. Previous work involving the implantation of polymethylmethacrylate (PMMA) rings, allograft corneal tissue, and hydrogels is well documented. One of the ring devices involves a split ring design which is inserted into a channel previously dissected in the stromal layer of the cornea. A minimally invasive incision is used both for producing the channel and for inserting the implant. See, for instance, the use of PMMA intrastromal rings in U.S. Patent Nos. 4,452,235 to Reynolds; 4,671,276 to Reynolds; 4,766,895 to Reynolds; and 4,961,744 to Kilmer et al. Surgical methods for the correction of such disorders are known. Such methods include radial keratotomy (see, e.g., U.S. Patent Nos. 4,815,463 and 4,688,570) and laser corneal ablation (see, e.g., U.S. Patent No. 4,941,093).

There are other procedures for reshaping the surface of the cornea. Some involve surgery; others do not. Two patents dealing with the nonsurgical reshaping of the cornea are U.S. Patent Nos. 4,326,529 to Doss, et al. and 4,381,007 to Doss. Both of these patents deal with the use of radio frequency energy to reshape the cornea of an eye. These involve the use of RF probes which are introduced non-invasively onto the cornea. They each involve an RF generating source which is placed on the anterior surface of the cornea and utilize saline solution to cool the corneal surface as the radio frequency current enters the eye. The RF apparently heats various stroma within the cornea and thereby reshapes the cornea as a biological response to the heat produced by the RF.

Other invasive ophthalmic surgical devices include U.S. Patent No. 4,805,616, to Pao, which describes a bipolar probe device used in ophthalmic surgery. The device is only described in the performance of anterior capsulotomies. In that procedure, a limbal incision is made and the active probe tip is inserted between the anterior capsule of the eye's lens and the corneal endothelium. The anterior capsule is sequentially coagulated, becomes extremely friable, and then is removed by mechanical

penetration with an additional mechanical device. No mention of treatment of a cornea is found.

Similarly, two patents to Easley et al., U.S. Patent Nos. 5,201,730 and 5,203,353, show devices for penetrating and working in the vitreous humor of an eye using combination stripping tools and aspirators. The disclosed instrument may also have a bipolar diathermy device with an exterior needle surrounding and coaxial to a fiberoptic member. The diathermy device is used only to coagulate bleeding vessels found on the retinal surface or beneath preretinal membranes. No mention of treating the cornea is mentioned.

Two related applications, U.S. Patent No. 5,025,811 to Dobrogowski et al., and 5,174,304, to Latina et al., show noninvasive methods for focal transcleral destruction of living human eye tissue. In general, these devices and their underlying procedures involve the use of electric currents for ablating eye tissue, particularly the ciliary process. Again, no mention of cornea treatment is seen.

This invention involves the introduction of an electrosurgical probe into the layers of the cornea to modify local sections of that corneal mass.

There are a variety of electrosurgical devices known. For instance, Hetzel, U.S. Patent No. 4,033,351, shows a bipolar cutting electrode for high frequency surgery. The electrode shows what is said to be an improved electrode design having a number of metal tips.

U.S. Patent No. 4,202,337, to Hren et al., shows a similar electrosurgical device for cutting or coagulation. It has a nonconductive handle with a blade assembly having a number of electrodes and an insulation member separating the various electrodes.

A similar and related patent to Degler Jr. et al., U.S. Patent No. 4,228,800, shows an electrosurgical knife in which the blade assembly has a center electrode of specified thickness, insulation members secured to the center electrode, and a number of side electrodes secured to the insulation members. None of these devices discuss practice of a surgical procedure upon the posterior regions of a cornea.

U.S. Patent No. 4,799,478, to Fedorov et al. teaches a device for the coagulation of biological tissues, preferably corneal tissue. The device disclosed by Fedorov et al. appears to be merely a heating device with a manner of carefully controlling

the depth to which the heater or coagulator is introduced. The device is said to be useful for coagulation of biological tissue and the concept of changing "the curvature" of "eye tissues, e.g., cornea" is noted. The patent mentions the need for high accuracy to reach the goal of "to carry out coagulation of the eye cornea to a specific depth." Although it is not clear what result Fedorov et al. wishes to obtain in this first patent, Fedorov et al. in U.S. Patent No. 4,907,587, mentions the use of thermal coagulation of the cornea along certain corneal surfaces to correct various optical aberrations in the eye. It should be noted that neither of these patents suggests the use of ablation or desiccation from the reverse side of the Bowman's layer to effect any change in the anterior corneal surface.

Summary of the Invention

An aspect of the invention provides a method of altering the shape of the cornea, often, the anterior surface curvature of the cornea. The invention also includes certain electrosurgical probe configurations useful in this process. The procedure, in its preferred variations, does not entail significant surgical modification of the anterior corneal surface or of the Bowman's layer of the eye, except, in certain situations, adding surface incisions to act either as a stress relief function or to provide access for the electrosurgical probe.

An electrosurgical probe is a significant aspect of this invention. It is used, preferably in desiccation or ablation mode, to change the volume of the mass of the cornea posterior to the Bowman's layer and found in the stromal regions of the cornea. By selectively modifying the volume of these regions, small amounts of the cornea may be controllably removed or shrunk and, upon removal of the electrosurgical probe from the cornea, the curvature of the anterior surface of the cornea will have changed and the refractive path of light entering the eye will be changed. As noted above, surface incisions may later be added to permit the anterior of the cornea, in particular, Bowman's layer, to conform to the underlying corneal tissue removal (volume change), thereby allowing for change in anterior corneal curvature.

The inventive procedure may be used for the treatment of hyperopia (farsightedness) or myopia. In this procedure, a small incision or access site may be made in the anterior surface of the cornea, which incision extends down through the Bowman's

layer or through the sclera and into the intrastromal volume of the cornea. An electrosurgical probe may be introduced through the incision and guided around within the corneal stroma from the outer periphery of the cornea. Activation of the electrosurgical probe in an ablation mode will cause vaporization of the regions of the cornea adjacent to the active areas of the probe. Activating the probe in a desiccation mode will shrink or necrose the region of the cornea adjacent to the active areas of the probe. After an appropriate necrosis, removal or shrinking of material is accomplished, the probe is removed and the anterior surface then relaxes to conform to the collapse or shrinkage of tissue formed by electrosurgical treatment of the corneal stromal tissue. In some instances, a modest incision in the anterior of the cornea may be desirable to allow curvature relaxation of the corneal anterior surface.

Another preferred procedure includes the alleviation of astigmatism by similar procedure. Small partial depth incisions may be made into the anterior surface of the cornea through Bowman's layer or through the sclera adjacent to the cornea to get under Bowman's layer, but not reaching so far as the posterior corneal surface or the anterior chamber. In a general sense, these initial incisions are made in the regions of the cornea or sclera to allow the electrosurgical probe to reach the corneal mass below the anterior surface which must be reduced to produce a symmetric corneal surface. In any event, an electrosurgical probe is then introduced through the incisions and a selected amount of material is removed or desiccated to alleviate the nonregularity of the corneal anterior surface.

Also as a part of this invention are certain monopolar, bipolar, and sesquipolar electrosurgical probe designs which are especially suitable for producing the specific tissue removal patterns desired in this procedure.

Also as part of this invention are certain variable-height active site electrosurgical probe designs. In one embodiment the active site of the electrosurgical probe is affixed to the top of a piston which can be raised and lowered within the nonconductive material of the electrosurgical probe. In this manner the height of the active site above the nonconductive portion of the probe can be varied, thereby allowing the surgeon to vary the depth of tissue removed during a procedure. Several possible means of raising and lowering the piston within the nonconductive probe are disclosed including

pneumatically raising and lowering the piston. Another possible means of raising and lowering the piston includes the use of a thermal expansion element which raises and lowers the piston as the thermal expansion element expands and contracts.

In another embodiment of the present invention a pneumatic balloon-type variable height electrosurgical probe is utilized where the active site region is raised and lowered in relation to the nonconductive portion of the electrosurgical probe by pneumatically inflating the balloon to which the active site is attached. In this manner the height of the active site above the nonconductive portion of the probe can be varied, thereby allowing the surgeon to vary the depth of tissue removed during a procedure. In the pneumatic balloon-type variable height electrosurgical probe the active site region can be formed from one or several strips of conductive material affixed to the balloon material by an adhesive in such a configuration to allow the balloon material to expand and contract during the raising and lowering of the active site region. In another embodiment, the active site region is formed by depositing a thin film of conductive material on the balloon material in such a manner to allow the balloon to expand and contract.

Brief Description of the Drawings

Figure 1 is a schematic illustration of a horizontal section of the eye.

Figure 2 is a schematic illustration of the anterior portion of the eye, showing various layers of the cornea.

Figures 3A to **3E** show a schematic process for treatment of hyperopia using the procedure of this invention.

Figures 4A to **4D** show schematic diagrams of astigmatic and normal eyes.

Figures 5-11 A and **B** show top and side views of inventive circular RF electrosurgical probes.

Figures 5-9 C and **D** show side views of alternative embodiments of inventive circular RF electrosurgical probes.

Figures 12-19 A and **B** show top and side views of inventive straight RF electrosurgical probes.

Figures 12-14 C and **D** show side views of alternative embodiments of inventive straight RF electrosurgical probes.

Figures 17C and **D** are top views of alternative embodiments of straight RF electrosurgical probes.

Figures 20 A and **B**, and **21 A, B** and **C** show top (A and C) and side (B) views of inventive disc and washer RF electrosurgical probes.

Figures 20C and **20D** are side sectional views of alternative embodiments of the probe of **Figure 20A**.

Figures 21D and **21E** are side sectional views of alternative embodiments of the probe of **Figure 21A**.

Figures 21F and **21G** are side sectional views of alternative embodiments of the probe of **Figure 21C**.

Figures 22A and **B** illustrate sesquipolar probe configurations.

Figures 23A-G are schematic diagrams showing top views of eyes wherein various processes for electrosurgically altering corneal curvature have been carried out.

Figures 24A-F illustrate an apparatus for positioning a circular electrosurgical probe to perform corneal tissue removal according to the present invention.

Figures 25-34 A and **B** show top views of inventive circular RF electrosurgical probes with inwardly-directed contact end portions and side views of the inwardly-directed contact end portions.

Figures 25-28 C and **D** show side views of alternative embodiments of inwardly-directed contact end portions of inventive circular RF electrosurgical probes with inwardly-directed contact end portions.

Figure 35 shows a complementary pair of inventive circular RF electrosurgical probes with inwardly-directed contact end portions.

Figure 36A is a side view of an electrosurgical probe having a variable-height active site controlled by a pneumatically activated piston.

Figures 36B & C are cross-sectional side views of an electrosurgical probe having a variable-height active site controlled by a pneumatically activated piston as shown in **Figure 36A**.

Figure 36 D is a cross-sectional side view of a piston-type variable-height probe as in **Figures 36A-C** with a return spring for lowering the piston.

Figure 36E is a side view of an electrosurgical probe with a rounded active site region.

Figure 36F is a cross-sectional side view of an electrosurgical probe with a piston adapted to accept different active site regions of differing size and shape.

Figure 36G is a cross-sectional side view of a piston-type variable-height active site electrosurgical probe which is adjusted by a thermal expansion element.

Figure 37A is a side view of an electrosurgical probe having a variable-height active site controlled by a pneumatically activated balloon.

Figure 37B is a top view of a pneumatic balloon type variable-height active site electrosurgical probe.

Figure 37C is a cross-sectional side view of a pneumatic balloon-type variable-height active site electrosurgical probe.

Figure 37D is a top view of a pneumatic balloon-type variable-height active site electrosurgical probe having an active site formed from multiple conductive strips.

Figure 37E is a cross-sectional side view of a pneumatic balloon-type variable-height active site electrosurgical probe utilizing a full balloon within a pressure chamber.

Figure 37F is a cross-sectional side view of a pneumatic balloon-type variable-height active site electrosurgical probe utilizing an active site that is sputter-deposited onto the surface of a balloon.

Figure 38 shows a microprocessor control loop for the probe in accordance with an aspect of the invention.

Detailed Description of the Invention

Prior to explaining the details of the inventive procedures and devices, a short explanation of the physiology of the eye is needed.

Figure 1 shows a horizontal cross-section of the eye with the globe (11) of the eye resembling a sphere with an anterior bulged spherical portion representing the cornea (12).

The globe (11) of the eye consists of three concentric coverings enclosing the various transparent media through which the light must pass before reaching the light-

sensitive retina (18). The outermost covering is a fibrous protective portion the posterior five-sixths of which is white and opaque and called the sclera (13), and sometimes referred to as the white of the eye where visible to the front. The anterior one-sixth of this outer layer is the transparent cornea (12).

A middle covering is mainly vascular and nutritive in function and is made up of the choroid, ciliary body (16), and iris (17). The choroid generally functions to maintain the retina (18). The ciliary body (16) is involved in suspending the lens (21) and accommodation of the lens. The iris (17) is the most anterior portion of the middle covering of the eye and is arranged in a frontal plane. It is a thin circular disc similar in function to the diaphragm of a camera, and is perforated near its center by a circular aperture called the pupil (19). The size of the pupil varies to regulate the amount of light which reaches the retina (18). It contracts also to accommodation, which serves to sharpen the focus by diminishing spherical aberration. The iris divides the space between the cornea (12) and the lens (21) into an anterior chamber (22) and the posterior chamber (23). The innermost portion of covering is the retina (18), consisting of nerve elements which form the true receptive portion for visual impressions.

The retina (18) is a part of the brain arising as an outgrowth from the fore-brain, with the optic nerve (24) serving as a fiber tract connecting the retina part of the brain with the fore-brain. A layer of rods and cones, lying just beneath a pigmented epithelium on the anterior wall of the retina serve as visual cells or photoreceptors which transform physical energy (light) into nerve impulses. The vitreous body (26) is a transparent gelatinous mass which fills the posterior four-fifths of the globe (11). At its sides it supports the ciliary body (16) and the retina (18). A frontal saucer-shaped depression houses the lens.

The lens (21) of the eye is a transparent bi-convex body of crystalline appearance placed between the iris (17) and vitreous body (26). Its axial diameter varies markedly with accommodation. A ciliary zonule (27), consisting of transparent fibers passing between the ciliary body (16) and lens (21) serves to hold the lens (21) in position and enables the ciliary muscle to act on it.

Referring again to the cornea (12), this outermost fibrous transparent coating resembles a watch glass. Its curvature is somewhat greater than the rest of the globe and is

ideally spherical in nature. However, often it is more curved in one meridian than another giving rise to astigmatism. Most of the refraction of the eye takes place through the cornea.

Figure 2 is a more detailed drawing of the anterior portion of the globe showing the various layers of the cornea (12) making up the epithelium (31).

An anterior limiting lamella (33), referred to as Bowman's membrane or layer, is positioned between the epithelium (31) and the stroma (32) of the cornea. The various stroma (32) between the Bowman's layer (33) and the Descemet's membrane (34) are referred to as the corneal mass. The corneal stroma (32) are made up of lamellae having bands of fibrils parallel to each other and crossing the whole of the cornea. While most of the fibrous bands are parallel to the surface, some are oblique, especially anteriorly. A posterior limiting lamella (34) is referred to as Descemet's membrane. It is a strong membrane sharply defined from the stroma (32) and resistant to pathological processes of the cornea.

The endothelium (36) is the most posterior layer of the cornea and consists of a single layer of cells and function to maintain transparency of the cornea (12). These epithelial cells are rich in glycogen, enzymes and acetylcholine and their activity regulates the transport of water and electrolytes through the lamellae of the cornea (12). The limbus (37) is the transition zone between the conjunctiva (38) and sclera on the one hand and the cornea (12) on the other.

There are a variety of different electrical surgical delivery probes which would be suitable in this invention. In general, there are two distinct electrosurgical delivery probe types: the monopolar probe and the bipolar probe. An in-between electrosurgical configuration applicable to this invention also exists and is known as sesquipolar. In each instance, some section of the human body is used to complete a circuit between one pole and the other. In the monopolar probe device, there is a single active contact which is inserted or otherwise contacted with the human body and it is the site at which some body activity, e.g., desiccation, ablation, necrosis, fulguration, or the like, takes place. To complete the circuit in a monopolar device, there must be another contact which is inactive and placed against the body in a location from the active contact. By "inactive" is meant that only an insignificant temperature rise occurs at that contact point. One such

method of insuring that the inactive electrode is in fact "inactive" is to make it quite large in area. This causes the current to spread over a large area for completion of the circuit.

A bipolar electrode typically has two equal area active electrodes contained in the same electrode probe-handle structure. This symmetric bipolar electrode design produces a significant temperature rise at both electrodes.

In a monopolar or sesquipolar configuration, only one electrode has an area of tissue contact producing significant temperature rise. Unlike the monopolar configuration, however, the sesquipolar return electrode is not so remote, and thereby limits current flow through the body to the nearby return electrode. The return electrode area in the sesquipolar configuration electrode is usually at least three times the area of the active electrode and produces little or no tissue effect. In some designs, the sesquipolar return electrode may be found on the electrode probe-handle structure while on other designs it may be separately located in a non-remote region of the body.

There are a variety of effects that may occur depending upon the electrosurgical mode desired. For instance, there are both high temperature and low temperature desiccation effects when the active electrosurgical probe contact(s) are used to promote tissue desiccation. The resistance of the tissue in contact with the active probe electrode obviously varies with the tissue temperature and water content of the tissue. A low temperature desiccation effect involves heating such that the temperature-time product causes tissue necrosis with little immediate denaturation or discoloration of the tissue. A high temperature desiccation includes heating tissue near the conducting probe contact to approach or slightly exceed 100° C. In the low temperature variation of this procedure, there is a transient decrease in local tissue impedance with little drying of tissue. But in the high temperature variation, there are significant increases in local tissue impedance and also significant in local tissue desiccation.

In the ablation mode, the electrosurgical energy density delivered largely causes the tissue near the probe contact to vaporize. The temperature at the electrode/tissue interface is increased significantly past the point of steam formation. The effect of electrical resistance varies during a specific radio frequency (RF) cycle and although there is sparking, carbonization is not usually significant and the effects of the device are relatively rapid.

Electrosurgical ablation and cutting produce an effect where a thin layer of tissue is vaporized (cutting) or where a larger section of tissue is vaporized (ablation). The line between "cutting" and "ablation" is not always clear.

Blended mode is essentially a combination of the cutting and coagulation (desiccation) modes. In blended mode, cutting or ablation with hemostasis is achieved.

In the procedure specified below as the invention, the electrosurgical probes may be operated in cutting, ablation, desiccation or blended modes. Herein, the term "volume change" or "volume modification" refers to the corneal mass being either necrosed, desiccated, ablated or subject to some combination thereof.

It is quite rare that the current flow through the device is DC. The current is typically a very high frequency alternating current, typically on the order of 500KHz or more. Additionally, the RF energy is often delivered in a pulsed or in a more continuous, non-pulsed operation depending on the exact effects desired. Some residual heating will take place no matter which course is taken. For further information concerning the electrical characteristics of electrosurgical waveforms, and electrosurgery in general, please refer to J.A. Pearce, Electrosurgery, John Wiley & Sons, 1986; U.S. Patent No. 4,438,766 to Bowers; the SSE2K Electrosurgical Generator Service and Instruction Manuals (1982, 1980), the SSE2L Electrosurgical Generator Instruction Manual (1991), and the Force 2 Electrosurgical Generator Instruction Manual (1993), Valleylab. These references are incorporated by reference herein in their entireties.

With this lengthy background in place, please refer to **Figures 3A** through **3D**. This series of figures shows, in schematic fashion, one procedure for treating hyperopia (farsightedness), myopia, or astigmatism. This schematic procedure shows features which may be common to all of the processes of this invention. Generically, the procedure includes the step of producing one or more incisions, often towards the periphery of the cornea. These incisions penetrate Bowman's layer in the anterior surface of the cornea and extend down into, as defined above, "the corneal mass" or "corneal volume." It is also contemplated that the electrosurgical probe may be inserted into the corneal volume without penetration of the anterior surface of the cornea, e.g., by access through a partial depth incision made in the sclera next to the cornea.

In any event, if an anterior access partial depth incision is contemplated, an optional step at this point may be the insertion of a non-electrosurgical lamellar separator to separate the various stroma lamellae within the cornea at the depth of the entry incision. This allows the subsequent step of inserting the electrosurgical probe to take place with greater ease. The probe itself may serve the function of intralamellar separator, if so desired.

The electrosurgical probe is introduced into the stromal lamellar cavity so produced. Depending upon the design of the inserted electrosurgical probe and on the refractive effect desired, the probe is moved inside the intralamellar space previously formed and activated to desiccate or ablate specific geometric regions of the cornea.

The probe may be energized by a common electrosurgical generator such as the Force 2 manufactured by Valleylab, Inc. The generator includes settings for providing the appropriate electrosurgical waveforms for cutting, coagulation or blended modes. The wave shape for each mode is specified in the Valleylab generator manual. Cutting is performed with a 510KHz continuous sinusoid. Coagulation (desiccation) employs a 510KHz damped sinusoidal burst with a repetition frequency of 31KHz. In blended modes, the generator outputs a 510KHz sinusoidal burst at various duty cycles recurring at 31KHz. Those skilled in the art will recognize that the present invention is not limited to the generators or particular wave shapes and corresponding electrical characteristics disclosed herein.

The probe initially may be energized at a low power setting (*e.g.*, 5 watts or lower) for approximately 1-5 seconds or longer. During activation of the probe, the surgeon observes the volume reduction process to ensure that tissue is being safely removed or shrunk from the proper corneal regions. Typically, this observation may be performed in real time through an ophthalmic microscope.

Desirably, after the completion of the corneal volume reduction step, the curvature of the corneal surface is then measured. Curvature is typically measured after the probe has been removed to avoid distortion of the corneal surface by the probe itself. One common method for measuring corneal curvature employs the Placido ring technique embodied in the Corneal Topography System manufactured by Eyesys of Houston, Texas. Curvature may also be measured using the technique described in allowed U.S. Patent

Application Ser. No. 08/200,241, assigned to the assignee of the present invention, and incorporated by reference herein. The procedure may be repeated if insufficient correction has occurred. When repeating the procedure, the surgeon may increase the output power to reduce a greater volume of tissue until the desired effect is achieved. If needed, Bowman's layer and a small amount of underlying stromal tissue may be lightly cut on the anterior surface adjacent to or above the site of the volume reduction to allow the anterior corneal surface to change.

Returning to the specifics of **Figures 3A** to **3D**, **Figure 3A** shows an eye (100) having a pupil (102) and a cornea (104). In the outer radius of cornea (104) are two small partial depth incisions (106) which have been cut through Bowman's layer into the corneal mass as shown in **Figures 1** and **2**. These incisions may be cut radially or circumferentially and are shown for discussion purposes to be radial.

It should be understood, however, that although two access partial depth incisions (106) have been portrayed in **Figure 3A**, the number of such access sites (106) is not important. If a semi-circular lamellar separator (108) as shown in **Figure 3B** is used, then the number of access sites (106) may be desirably two in number. If lamellar separators of shorter arc segments are used, more numerous slits may be desired. If a nearly circular lamellar separator or electrosurgical probe is used, a single access site (106) may be sufficient.

Figure 3B shows the introduction of the optional dissector blade or lamellar separator (108) to separate the lamella found in the cornea. Alternatively, the probe itself may be used to separate the lamella. The separator (108) is rotated until a circular channel is made in the corneal periphery, and is rotated back out of the eye. A similar procedure takes place on the other access site as shown in **Figures 3A** and **3B**. **Figure 3C** shows the insertion of an electrosurgical probe (110) into the route formed in the intrastromal region shown in **Figure 3B**. The probe may be energized following complete insertion or may be energized in a stop, move and activate mode. The step of removing and/or shrinking tissue is continued until sufficient tissue has been ablated or desiccated to achieve the desired refractive effects.

Figure 3D shows the eye (100) after completion of the ablation procedure. It may be desirable to place a small stitch (112) or biocompatible glues developed for

wound closure, such as fibrinogen, cyanoacrylate, etc. in any access site (106) in the cornea to ensure healing of the access site and minimize the potential for infection. **Figure 3E** shows the eye (100) following relief cuts (114) that may be necessary in some instances to allow the anterior corneal surface to more closely conform to the underlying corneal tissue removal (volume change) thereby allowing for greater change in anterior corneal curvature. These relief cuts may be circumferential as shown or they may be radial depending on the desired refractive effect. Further, the relief cuts may be continuous or may be interrupted as shown. In any case, these cuts may penetrate Bowman's layer and possibly a portion of the underlying corneal stroma.

The above-description generally indicates the method of the present invention. Specific probe configurations and method of treatment will be described in the examples below.

It should be apparent from the description above, that the step of desiccating, necrosing or ablating the tissue from within the corneal mass lessens the volume of that mass in specific regions of the cornea. Consequently, the anterior sections of the cornea will become flatter or steeper and will alleviate the improper previous refraction of light. Some of the possible changes in corneal thickness and their relationship to the radius of curvature of the central corneal surface are described in Jose Barraquer: Father of Modern Refractive Keratoplasty, in Refractive and Corneal Surgery, Vol. 5, May/June 1989, pages 177-193, which is hereby incorporated by reference in its entirety. This paper describes the so-called "Law of Thickness" which indicates that when corneal volume is reduced in the periphery, central corneal steepening occurs and when a volume of tissue is removed in the center, central corneal flattening occurs. The inventive electrosurgical method and devices aim to reduce corneal volume in controlled geometric areas of the corneal stroma to achieve refractive correction.

The method and devices of the present invention may also be useful in the treatment of astigmatism. Astigmatism occurs, generally, when the curvature of the anterior surface of the cornea is not regular as one passes about the meridians on the anterior surface of the cornea resulting in a steep and flat axis (the astigmatic axis). **Figure 4A** and **4B** are schematic perspective views that show an astigmatic and normal eye, respectively. In an astigmatic eye, two axes are generally identified, corresponding to the

steepest (120) and flattest (122) axis of curvature. The steepest axis is also known as the axis of astigmatism (120). To correct astigmatism using this invention, one must flatten the curvature of the astigmatic axis such that the cornea becomes reasonably symmetrical and more spherical. **Figure 4B** shows a normal eye, that is, one in which the curvature of all axes are the same. **Figures 4C** and **4D** show schematic topographical curvature maps of an astigmatic and of a non-astigmatic eye, respectively. In **Figure 4C**, region 130 is the steep region whereas region 132 is flatter.

Other configurations of access sites and controlled removal of corneal tissue are apparent. These will be discussed for particular applications in the examples below. Further, it should be apparent to one appreciating the design of such electrosurgical RF probes, that the shape need not be nearly circular. It may be, much in the same way as were the lamellar separators (108) in **Figure 3B**, that the probes have lesser arc length or are straight for alleviating hyperopia. In fact, for treating hyperopia or other maladies, the probe may be of any convenient shape designed to ablate the tissue at hand. Such shapes will be discussed in more detail below. Further it may be noted that the handles of the probes may be straight or bent. The handle also may be a circular barrel to facilitate the vision of the surgeon. A bent handle may allow greater facility of use within the small confines found behind an access site as shown in the above drawings. Additionally, the procedures and devices of the present invention may be useful in the treatment of more than one indication; for example myopia and astigmatism or hyperopia and astigmatism.

Figures 5-11 A and **B** show top (A) and side (B) views of circular electrosurgical probes suitable for use in the schematic procedure described above. The terms "circular probe" and "substantially hook-shaped probe" refer to an arcuate or substantially circular probe or a probe that otherwise subtends any radial angle of a substantially circular geometric figure. Note that these circular probes may form part of a complementary set, as described below with respect to the circular probes of **Figures 25**, et seq.

Figures 5A and **B** show a circular RF electrosurgical probe with two active sites that operate in monopolar or sesquipolar modes. The probe (200) includes a shaft (202) and two active sites (204), each active site having an arc of less than about 180°, preferably less than about 90°. The probe has an inner diameter of approximately 6.5 mm

and an outer diameter of approximately 8.5 mm. The single source of RF energy (206) is fed in through the insulator (208) making up the probe (200). **Figures 6A** and **B** show a circular RF electrosurgical probe (210) with a single active site (212) at the tip. Again, the single source of RF energy (214) is fed in through the insulator making up the probe. **Figure 7A** and **7B** show a circular RF electrosurgical probe (220) with a single active site (222) extending the length of the circular portion of the probe. Once more, the single source of RF energy (224) is fed in through the insulator (226) making up the probe. **Figures 8A** and **B** show a circular RF electrosurgical probe (230) with two active sites (232) near the tip of the probe that operate in bipolar fashion. Two sources of RF energy (234 and 236) are fed in through the insulator (238) making up the probe. **Figures 9A** and **B** show a circular RF electrosurgical probe (240) with a single active site (242) near the tip, the active site shown in **Figure 9A** to be on the top part of the probe. A single source of RF energy (244) is fed in through the insulator (246). **Figures 10A** and **B** and **11A** and **11B** show other circular RF electrosurgical probes (250 and 260 respectively) with single active sites (252 and 262 respectively) near the tips of the probes. A single source of RF energy (254 and 264) is fed in through each probe. **Figure 10B** shows the active site (252) to be located at the tip but exposed on one side and **Figure 11B** shows the active site (262) to be located at the tip but insulated on the top and thus exposed on one side only. Both probes depicted in **Figures 10 A** and **B** and **11 A** and **B** are designed to contact tissue in either the forward or retracting direction to the active site on the probe, the retracting direction.

Figures 5-9 C and **D** show side views of circular electrosurgical probes in which the active sites applied to tissue are raised above a substantial portion of the nonconductive area of the probe. The height of the raised active site controls the depth of the tissue removed. This height is approximately in the range of 0.0-0.55 mm. The raised active site pushes tissue in contact therewith above the larger nonconductive area of the probe. The unraised nonconductive portion acts as a backstop or footplate with respect to the raised active site. In the absence of a raised active site, uniform pressure must be maintained against the tissue in order to remove tissue of uniform depth. With the raised active site of the present invention, uniform depth is easier to achieve without fine control of the applied pressure because the footplate (larger nonconductive area) acts as a stop to

prevent the active site from advancing into the tissue to a depth deeper than the height of the raised active site. The active site also may be lower than contact end. That is, the active site may be varied within a well or sunken area.

A set of probes having active sites raised to different heights may be provided, so that the surgeon may select the proper probe depending upon the depth (and therefore volume) of tissue to be removed. During performance of a procedure, the surgeon may use multiple probes, e.g., increasing in active site height, until the desired depth of tissue removal is achieved. Alternatively, a single probe may be adapted for use with removable active sites of different heights. The active sites may be coupled to the rest of the probe by any number of well known removable means, including but not limited to pressfit, snap engagement screws, or slideable mounts.

A probe having a variable height active site may be provided, allowing the surgeon to adjust the height of the active site depending on the depth (and therefore the volume) of tissue to be removed. During performance of a procedure, the surgeon may vary the height of the active site until the desired depth of tissue removal is achieved.

More particularly, the height of the active site of a probe can be varied by several possible mechanisms. **Figures 36A-36G** show one particular embodiment where an active site (3601) is a conductive region located on the top of a piston (3602). Raising and lowering the piston within an insulator making up a probe (3603) varies the height of the active site allowing the surgeon to control the depth of tissue material removed.

The piston (3602) in the embodiments shown in **Figure 36A-36G** can be raised and lowered by several alternative means. In one embodiment, shown in **Figure 36B**, the piston (3602) is raised and lowered pneumatically within a hole (3606). The piston (3602) forms an airtight seal on a pressure chamber (3604) located within the probe, which is connected to an air pressure line (3605). Several possible means of forming an airtight seal can be employed including, but not limited to, use of O-ring seals, or other covenient or suitable means for providing an airtight seal between the piston and the probe such as a flexible polymer coating on the perimeter of the piston. The hole (3606) is formed in the wall of the pressure chamber (3604) and extends through the nonconducting probe (3603) to the exterior of the probe. The piston (3602) moves within the hole (3606) to vary the height of the active site (3601) above the surface of the nonconductive probe

(3603). As pressure within the pressure chamber (3604) increases, the piston (3602) is forced in an upward direction, thereby increasing the height of the active site (3601) above the nonconductive portion of the probe (3603). Conversely, reducing air pressure within the chamber causes the piston to move in a downward direction , thereby reducing the height of the active site (3601) above the nonconductive portion of the probe (3603). In this manner the pressure chamber (3604) and air act as an actuator to raise and lower the piston (3602). As shown in **Figure 36C**, a flange portion (3608) of the probe (3603) comes in contact with a piston flange (3607) to prevent the piston (3602) from "popping out" of the probe (3603) when excessive air pressure is applied by the surgeon. The air pressure line (3605) passes through the nonconductive material making up the probe (3603) to the probe handle. The line (3605) is attached to and is connected to a pressure regulator (not shown), which can be controlled by the surgeon to change the pressure within the pressure chamber (3604), thereby adjusting the height of the active site (3601). While the present invention utilizes air, other gases or even liquids can be used to increase or decrease pressure within the pressure chamber (3604), thereby raising or lowering the piston (3602), respectively. It is important that there be an airtight seal between the piston (3602) and the nonconductive portion of the probe (3603) to prevent air, or other gasses within the pressure chamber, from leaking into the corneal tissue during the procedure. An RF energy line (3609) passes through the nonconductive material of the probe (3603) and through the piston (3602) to connect to the active site (3601).

An alternate embodiment of the piston-type variable-height electrosurgical probe is shown in **Figure 36D**, a cross-sectional side view, wherein a return spring (3610) is used to bias or to provide a force to lower the piston (3602) when the pressure within the pressure chamber (3604) decreases. The spring (3610) biases the piston (3602) in a direction of decreasing the height of the active site (3601) i.e. in a downward direction. The piston (3602) has a lower flange (3607) which forms an substantially airtight seal against the side of the nonconductive portion of the probe (3603), thus preventing pressurized air within the pressure chamber (3604) from escaping at an appreciable rate. The spring (3610) is coiled around the piston (3602) and pushes at one end against the piston flange (3607) and at the other end against a probe flange (3608). As pressure within the pressure chamber (3604) decreases, the force of the spring pushing on the piston flange

(3607) causes the piston (3602) to move in a downward direction, thereby decreasing the height of the active site (3601) above the nonconductive portion of the probe (3603). Both the pressure chamber (3604) and the spring (3610) act as an actuator to raise and lower the piston (3602).

The active site (3601) of the piston-type variable-height probe shown in **Figures 36A-36G** is formed from a conductive layer, made from a material such as copper or stainless steel and having a thickness in a range of 10 microns to about 150 microns or thicker, which is attached to the upper surface of the piston (3602) by a heat resistant adhesive or other heat resistant fasteners. A heat resistant adhesive is used to prevent the active site (3601) from becoming dislodged during the repeated heating and cooling cycles of the ablation procedure. While the active site (3601) shown in **Figure 36A** is flat and circular, extending to cover the entire portion of the upper surface of the cylindrically shaped piston (3602), other embodiments could utilize other shapes and sizes for the active site region (3601) and the piston (3602). Additionally, a piston with a non-flat upper surface can be utilized to contour the shape of the active site region (3601), as shown in **Figure 36E,** wherein the piston (3602) has a rounded upper surface and the active site (3601) formed thereon has a rounded profile. Piston (3602) also may be fabricated from a suitable metal for improved heat sinking ability.

Another embodiment shown in **Figure 36F** utilizes a piston adapted to accept different active site regions of differing size or shape. As shown in **Figure 36F** an active site cap (3611) is held onto the piston (3602) by a pair of screws (3612). Alternatively, the cap may be affixed by a biocompatible glue, clips or other fasteners which are well known to those skilled in the art. RF energy is supplied to the active site through an RF connector (3613), which connects to an RF power supply line (3609). In this way a large active site region could be attached, by a screw or clip, to ablate larger areas of tissue while a small active site region could be used for the ablation of smaller volumes of tissue. Other shapes and sizes can be utilized to better adapt the probe to a specific application.

An alternate embodiment of the piston-type variable-height electrosurgical probe is shown in **Figure 36G**, wherein a thermal expansion element (3614) is located within the nonconductive portion of the probe (3603) and a piston (3602) with a conductive

active site area (3601) is located above and firmly attached to the thermal expansion element (3614). As the thermal expansion element expands, the piston moves in an upward direction, thereby increasing the height of the active site (3601) above the nonconductive portion of the probe (3603). Similarly, contraction by the thermal expansion element (3614) causes the piston (3602) to move downward, thereby lowering the height of the active site (3601). The thermal expansion element (3614) acts as an actuator to raise and lower the piston (3602). A separate power supply line (3615) is provided to the thermal expansion element (3614). The power supply line 3615 is coupled to a power supply (not shown). By varying the voltage applied to the element (3614), the surgeon can control the height of the active site (3601). It will be appreciated that element (3614) may comprise any well known material characterized by a useful coefficient of thermal expansion which enables the desired expansion/height to be achieved.

Figures 37A-37B show another embodiment of the present invention wherein an active site (3701) comprises a layer of conductive material attached to a balloon (3702). **Figure 37C** shows a side cross-sectional view of a probe (3703) shown in **Figures 37A-37B** and illustrates an RF energy line (3709), a pressure inlet line (3705), a pressure chamber (3704), and a circularly shaped hole (3706), which extends between the pressure chamber (3704) and the exterior of the probe (3703). The balloon (3702) is constructed from a layer of elastic material and is attached to the probe (3703) in such a manner as to form an airtight barrier over the hole (3706) between the pressure chamber (3704) and the exterior of the probe (3703). As shown in **Figure 37C**, the balloon (3702) is attached to the probe in such a manner that as pressure increases within the pressure chamber (3704) the balloon expands, thereby increasing the height of the active site above the nonconductive area of the probe (3703). Means for attaching the balloon (3702) to the edge of the hole (3706) include use of ultrasonic welding, laser welding or an adhesive or suitable mechanical clamping mechanism. For example, one embodiment of the present invention may utilize a ring-shaped clamp (not shown) which applies even pressure to hold the balloon (3702) securely in place and also provides an airtight seal between the balloon (3702) and the walls of the pressure chamber (3704). The ring-shaped clamp may be securely fastened to the nonconductive probe (3703) by four screws (3712) which screw from the exterior of the probe (3703).

Generally, several embodiments of the balloon-type variable height electrosurgical probe are shown in **Figures 37A-37F**. The active site (3701) shown in **Figure 37A-37B** is formed from a flexible layer of conductive material attached to the balloon (3702) by an adhesive. Alternatively, the conductive material of the active site (3701) can be sputter deposited on the balloon (3702) to form a flexible layer that expands with the balloon as the balloon is inflated, as shown in **Figure 37F**. In yet another embodiment of the present invention shown in **Figure 37D**, the active site (3701) is formed from strips of conductive material attached to the balloon (3702) by an adhesive. The sections of the balloon (3702) between the strips of conductive material are able to expand as pressure increases inside the balloon (3702). The spacing between the placement of the strips should be great enough to allow expansion of the balloon (3702) as pressure increases within the chamber (3704). To enable raising and lowering of the active site (3701). Each of the conductive strips is connected to an RF energy line (3709) which passes through the non-conductive portion of the probe (3703) from the handle of the probe. In each of the embodiments of the present invention shown in **Figures 37A-37F** the active site (3701) is connected to an RF energy line (3709).

Suitable materials for balloon construction include any elastic material such as a silicon, thermaplastic elastomers, rubber, neoprene or the same kind of materials used for an angioplasty balloon. The material chosen should be capable of expanding as pressure increases within the pressure chamber without allowing the gas or liquid within the pressure chamber to leak through the balloon material. Acceptable pressure ranges may be on the order of a few psi up to about 400 psi for specialized applications. Additionally, the adhesive material chosen to secure both the active site (3701) to the balloon (3702) and the balloon to the edge of the hole (3706) should be chosen such that it does not degrade the elasticity, structural integrity, or the ability of the balloon (3702) to seal against leaks from the pressure chamber (3704). While the cross sectional view of the probe (3703) shown in **Figure 37C** shows the balloon (3702) as a layer of flexible elastic material attached to the edge of the hole (3706), another embodiment shown in **Figure 37E** could utilize an entire balloon sac (3702) inserted into the pressure chamber (3706) and securely held within said pressure chamber (3706) in such a manner to prevent pressure from the pressure feed line (3705), connected to the opening of the balloon sac (3702), from escaping from the

pressure chamber (3706). Means for securely holding the balloon within the pressure chamber include the use of an adhesive which securely bonds the balloon to the walls of the pressure chamber (3704). Other securing means include a mechanical clamp holding the mouth of the balloon (3702) in place within the pressure chamber at the connection of the pressure chamber (3704) to the pressure line (3705). Various other clamping mechanisms are possible, which serve to securely anchor the balloon within the pressure chamber, thereby preventing the balloon from becoming dislodged from its position within the pressure chamber (3704).

In the embodiment shown in **Figure 37F** the active site (3701) is a layer of conductive material sputter deposited onto the balloon at low temperature to prevent melting or damaging the balloon (3702). Additionally, standard low temperature sputtering techniques can be employed to cool the balloon target during the sputtering process. Any biocompatible elastomeric material such as polyurethane or any material used for an angioplasty balloon can be used for the balloon, preferably with a thickness of approximately .001 inch. A layer of conductive material can be sputter deposited on the balloon to form the active site layer in accordance with conventional room temperature sputtering techniques which are well known. The important parameter is that the active site layer be thin enough to preserve the desired flexibility of the balloon. This process can be applied to all of the embodiments of the balloon-type variable-height electrosurgical probe.

The variable height active site electrosurgical probes shown in **Figures 36A-G** and **Figures 37A-F** are used by a surgeon to perform corneal tissue removal according to the procedure of the present invention. Once a probe, as shown in **Figures 36A-G** and **Figures 37A-F**, is inserted within the cornea, the surgeon may vary the height of the active site either by varying the pressure supplied to the probe through the air pressure line (3605) or (3705), by use of a pressure regulator (not shown), or by varying the current supplied to a thermal expansion element (3614) by two conductor power supply lines (3615) to the thermal expansion element.

The surgeon preferably is provided with a height v. pressure curve which is calibrated for each probe. This tells the surgeon precisely how much current to apply in order to achieve a desired height of the active site.

In accordance with an aspect of the invention, the height v. pressure curve may be embodied in a look up table in a microprocessor. As shown in **Figure 38** and, in accordance with standard control and active feedback techniques which are well known and can be implemented readily by one skilled in the art, a microprocessor 3800 and position sensor 3802 provide an active feedback control system. The active feedback control system indicates how far the probe 3804 is moved in terms of a height v. pressure curve (not shown) in response to a signal supplied from the position sensor 3802 which is coupled to the probe 3804. The feedback loop prevents the probe 3804 from being moved beyond a predetermined point to ensure a safe insertion point at all times.

The position sensor 3802 preferably comprises a transducer capable of critical linear displacement measurements. An example of such a displacement transducer is a differential variable reluctance transducer (DVRT) such as manufactured by MICROSTRAIN®, Inc. of Burlington, Vermont. Such DVRTs are extremely lightweight, small in size, and utilize flexible, elastic and biocompatible materials.

The displacement transducer/position sensor 3802 measures the position of the probe 3804. A conventional feedback control loop to the microprocessor 3800 then computes the change in pressure necessary to move the probe precisely to a desired position. The internal pressure of the corneal tissue amounts to about 60 mm of mercury. Thus a 1 psi increase in pressure supplied to the balloon as piston produces only a very small change in the height of the active site.

In **Figures 5-9 D**, a small nonconductive portion immediately adjacent to the active site is also raised above the larger nonconductive area. The raised nonconductive portion covers all or a part of the side area of the active site to limit the conductive area exposed to tissue. This prevents tissue removal from being caused by electrical energy from the covered side areas, thereby giving the surgeon greater assurance that tissue will be removed in a direction normal to the face of the active site and not in other, lateral directions spreading sideways from the raised active site. The insulation of the side areas also increases the current density associated with the face of the active site, providing more efficient tissue removal.

Figures 24 A-F illustrate an apparatus for positioning a circular electrosurgical probe to perform corneal tissue removal according to the procedure of the

present invention. The circular probe (2400) includes a circular contact end (2402) coupled to a support arm (2404) that is angled with respect to the plane of the circular contact end (2402). The angle may have a value of 0° to 900°. The angle is preferably between 0° and 800°, more preferably between 10° and 500° and most preferably about 340° (+/- 50°). This angle results in the support arm (2404) being generally perpendicular to the corneal surface when the circular contact end (2402) is introduced into the corneal stroma. This angle, although not absolutely critical, is desirable and has been found to prevent tearing of the epithelium during the corneal operation. The length of the support arm (2404) is sufficient so that the entire circular contact end is visible through the top of the barrel (2406) during use.

Figure 24B illustrates the circular contact end (2402) in greater detail. The contact end (2402) may be rectangular in cross-section as shown in **Figure 24B** or tapered on its smaller edge as shown in **Figure 24C**. The contact end may be of any convenient shape, including the rectangular cross-section of **Figure 24B** or the hexagonal cross-section of **Figure 24C** in which two opposite sides are longer than the remaining four.

The overall relationship of the sizes of the diameter of the arc (2408) of the contact end (2402) to the length of the barrel (2406) is desirably chosen so that the ratio of that length to the arc diameter is between 0.25:1 and 15:1; specifically between 0.4:1 and 1:1, at least about 1:1 and less than about 3:1; and at least about 3:1 but less than 15:1. These ratios allow easy manipulation by the surgeon. The contact end (2402) has two other physical parameters relevant to effective performance of the surgical procedure. Upon rotation of the barrel (2406), the contact end (2402) must move in a path which is substantially planar. The path of the contact end (2402) as it moves in the corneal intrastromal lamellar channel must not vary either up or down during the barrel (2406) rotation. The distance "a" shown in **Figure 24B** is chosen so that the contact end (2402) is centered about the axis (2410), which forms the center of the barrel (2406).

Similarly, the cone angle β (2412) is preferably 112° +/- 30°. Again, this permits the contact end (2402) to traverse a channel which is parallel to the lamella found in the corneal stroma. The cone angle β (2412) may, of course, vary a few degrees dependent on such variables as the size of the eye and the amount of correction required.

Preferably, all of the circular, disk-shaped, and washer-shaped probes described in this disclosure take on one of the cross-sectional shapes illustrated in **Figure 24B** or **24C**. The active sites of those probes can reside on the central flat portion and/or on the angled portion of the contact end of **Figure 24B** or **24C**.

Figure 24D is a side view of an insulated support base used in conjunction with the probe assembly of **Figure 24A**. The support base includes an annular circumcorneal vacuum ring (2450) and a cylindrical or central bore (2452) extending through the support base. The support base contains a viewing port (2454) to allow a surgeon to view the operational steps which take place at the corneal surface. The vacuum is brought in from a vacuum source line (2456) that is coupled to a vacuum pump (not shown). The vacuum ring (2450) is configured so that it meets with and seals to the front of the eye, rendering the support base relatively immobile when the support base is applied to the front of the eye and a suitable vacuum is applied to the vacuum source line (2456). The vacuum chamber forms an annular vacuum space across the front of the eye.

Figure 24E shows a bottom view of the support base in which the circumcorneal vacuum ring (2450) may be clearly viewed. The vacuum ring (2450) is made up of an inner wall (2458) terminating on its inside by the central bore (2452). The central bore (2452) is at least large enough to see the entirety of the circular contact end (2402). The central bore (2452) has an axis which substantially coincides with the axis of the circular contact end (2402). The central bore (2452) is desirably a length such that the ratio of the bore's length to its diameter is between 0.25:1 and 15:1; specifically between 0.4:1 and 1:1, at least about 1:1 and less than about 3:1; or at least about 3:1 up to about 15:1. Preferably, the ratio is about 2.5:1. This sizing allows easy manipulation by the surgeon. The outer vacuum ring wall (2460) desirably forms the outside of the support base. Interior to the vacuum ring (2450) may be one or more ridges (2462) which extend down to the corneal surface when the support base is attached to the eye. These ridges may be made of conductive material, while the surrounding support base structure, such as the inner wall (2458) and outer wall (2460), are made of insulating material. The ridges (2462) may be coupled to an electrosurgical generator (not shown). Using this configuration, the ridges (2462) may act as return electrodes when operating in sesquipolar mode. These return electrodes may be positioned to rest on the sclera or translimbal region of the eye.

Figure 24F shows an alternative arrangement of return electrodes comprised of radial vanes (2464) that extend downward through the vacuum ring (2450) to make contact with the sclera or translimbal region.

Figures 25-34 A and **B** show top (A) and side (B) views of circular (substantially hook-shaped) probes having inwardly-directed contact end portions suitable for use in the schematic procedure described above. **Figure 35** illustrates a complementary pair of probes used to modify an annular 360 degree channel of tissue. One probe of the pair is inserted and rotated in one direction to modify tissue, and then removed. The complementary probe is then inserted and rotated in the other direction to modify the remaining tissue in the channel, and then removed. Those skilled in the art will recognize that the circular probes of **Figures 25-34** may be employed as part of a complementary set, and may be easily modified to subtend any angle of a circle, not just 180 degrees as shown. The complementary probe subtends an angle of the circle equal to 360 degrees less the radial angle of the first probe, so that a full 360 degree volume of tissue can be ablated or desiccated. As described below, a complementary probe set to complete a 360 degree path may be required for treatment of hyperopia and myopia, but not necessarily for astigmatism.

These configurations allow high current density to be achieved with relatively low power due to the relatively small area of the active site. They are particularly appropriate as an alternative to the disc and washer shaped probes shown in **Figures 20** and **21**. In comparison, the latter probes require a higher power to achieve the same current density because of the larger area of their active sites. Further, the access site incision required for insertion of the probes of **Figure 25-32** is smaller, resulting in less trauma to the eye during the procedure.

Figures 25 A and **B** show a circular probe (265) having an inwardly-directed contact end portion (269) with a single active site (267). The active site shown in 25B may be open (uninsulated) only on top, or open on the top and the leading side, but insulated on the trailing side (as shown). In general, the sides and the top of the probes described herein may be insulated or open in different combinations. The leading and trailing sides are defined by the direction of rotation, here counterclockwise. The probe (265) includes a shaft (266) and an active site (267). The probe has an inner diameter of

approximately 6.5 mm and an outer diameter of approximately 8.5 mm. The inwardly-directed contact end portion is directed along the radial axis of the circular ring. The single source of RF energy (268) is fed in through the insulative contact end (266) making up the probe (265).

Figures 26A and **26B** show a circular probe (270) having an inwardly-directed contact end portion with a single active site (271) at the tip. Again, the single source of RF energy (272) is fed in through the insulator making up the probe.

Figures 27A and **27B** show a circular probe (275) having an inwardly-directed contact end portion with a single active site (276) extending the length of the inwardly-directed contact end portion of the probe. The active site can be of varying thickness, take on different shapes, and be angled within the insulated inwardly-directed portion. The active site shown in **Figure 27** is shown as a thin wire to achieve high current density, but may be broader. The active site may also contain bends instead of being straight, or may be angled within the insulated inwardly-directed portion as shown in **Figure 33**. Rotation of the active site during activation of the probe will remove a disk of corneal tissue for those probes where the active site extends all the way to the center of rotation. Once more, the single source of RF energy (277) is fed through the insulator making up the probe.

Figures 28A and **28B** show a circular probe (280) having an inwardly-directed contact end portion with two active sites (281) that operate in bipolar fashion near the tip of the inwardly-directed contact end portion. Two sources of RF energy (282 and 283) are fed in through the insulator making up the probe.

Figures 29 A and **B** show a circular probe (284) having an inwardly-directed contact end portion with a raised single active site (285) on the leading side with a raised insulated backstop (286) on the trailing side. **Figure 29** shows the active site raised with an open top (287), although this top side can also be insulated in an alternative embodiment. A single source of RF energy (288) is fed in through the probe.

Figures 30 A and **B** show a circular probe (289) having an inwardly-directed contact end portion with a single active site (290) located on the leading edge of the probe. As **Figure 30B** shows, the active site is open only on the leading side and not on the top or trailing sides.

Probe (291) in **Figure 31** is an alternative embodiment of probe (265) of **Figure 25** where the inwardly-directed contact end portion (293) is angled with respect to the radial axis of the circular portion (295). Note that the inwardly-directed portion may alternatively be angled into the area that is a reflection about the radius from the area in which the inwardly-directed portion of **Figure 31** lies. All of the active site configurations of probes (270), (275), (280), (284), (289), (298), (500), and (505) can be angled in a similar manner.

Probe (298) in **Figure 32** is another embodiment of probe (265) illustrating that the inwardly-directed contact end portion (296) can be of variable length. Rotation of this active site during activation of the probe will remove a wide annulus of corneal tissue.

Figures 33 A and **B** show an alternative embodiment of **Figures 27 A** and **B** where the active site (501) is angled rather than parallel to the sides of the inwardly-directed contact end portion.

Figures 34 A and **B** show a circular probe (505) having an inwardly-directed contact end portion with two active sites (506 and 507) which may operate in a time multiplexed fashion. Two sources of RF energy (508 and 509) are fed in through the insulator making up the probe. In one operational mode, active site (506) is activated during forward (counterclockwise in this example) rotation of the probe while active site (507) is off. During backward (clockwise) rotation, active site (507) is activated while active site (506) is off. The use of two smaller active sites rather one larger one allows for a higher current density to be achieved with relatively low power due to the smaller area of each active site.

Figures 25-28 C and **D** show alternative side views of inwardly-directed portions of circular probes with inwardly-directed contact ends where the active sites applied to tissue are raised above a substantial portion of the nonconductive area of the probe. The design and purpose of the raised active sites are the same as that for the circular probes described above. In **Figures 25-28 D**, a small nonconductive portion immediately adjacent to the active site is raised on two sides of the active site to limit the conductive area exposed to the tissue. The insulation can also cover the trailing side of the active site and/or the top of the active site to reduce the area further, leaving only the leading side exposed. Alternatively, all sides can be insulated to leave only the top side exposed. This

insulation around the active site ensures tissue removal normal only to the open faces of the active site and not in undesired lateral directions. The insulation also increases the current density associated with the open faces of the active site.

Figures 12-19 A and **B** show top (A) and side (B) views of straight electrosurgical probes suitable for use in the schematic procedure described above. **Figures 12A** and **B** show a straight RF surgical probe (300) with a single active site (302) extending along the length of the probe. A single source of RF energy (304) is fed through the probe. **Figures 13A** and **B** show a straight RF electrosurgical probe (310) with two active sites (312) extending along the length of the probe that operate in bipolar fashion. Two sources of RF energy (314 and 316) are fed in through the insulator (318) making up the probe.

Figures 14-19 A and **B** show other straight RF electrosurgical probes with single active sites near the tips of the probes. A single source of RF energy is fed in through each probe. **Figures 14 A** and **B** show the active site (322) to be located near the tip of the probe (320) and on top of the probe such that the active site is raised and pointed in the retracting direction of the probe. **Figures 15A** and **B** show the active site (332) similarly located near the tip of the probe. The end of the probe is raised and the active site (332) is located on the raised part of the tip pointing backwards, the active site being exposed on two sides. **Figures 16A** and **B** similarly show the active site (342) raised at the end of the probe pointing backwards (340), but the active site is imbedded in the insulating curve of the probe, thereby exposing the active site on one side only. **Figures 17A** and **B** show the active site (352) at the tip of a straight probe (350), the active site being exposed on one side on the tip portion alone. **Figures 18A** and **B** show the active site (362) near the end of a straight probe (360). The probe is broadened at the active site.

Figures 19A and **B** again show a straight RF electrosurgical probe (370) with a curved tip, with the active site (372) again raised and pointing backwards and slightly upwards the active site being exposed on one side on the tip portion alone. However, in this embodiment the active site is angled such that a portion (374) of the active site (372) extends beyond the curved tip. In this design, the ablation or desiccation takes place either as the device is pushed forward or as it is pulled backwards, or retracted from the lamellar separation channel.

Upon exposure to tissue and electrode activation, the active site will vaporize or desiccate the tissue. It may be desirable to provide a second lamellar channel to allow for the relief of gases produced by the probe when used in the ablation mode or to incorporate grooves in the probe portions that insert into the tissue to allow the escape of gases so produced.

Figures 12-14C and **D** are side views of the probes of **Figures 12-14A**, respectively, for alternative embodiments. In **Figures 12-14C**, the active sites are raised above the larger nonconductive areas. In **Figures 12-14D**, a small nonconductive portion immediately adjacent the active site is also raised above the larger nonconductive area. **Figures 17C** and **D** are top views of the probe of **Figure 17A** for an alternative embodiment. In **Figure 17C**, the active site is raised above the larger nonconductive area. In **Figure 17D**, a small nonconductive portion immediately adjacent the active site is also raised above the larger nonconductive area.

Figures 20 and **21 A** and **B** show top (A) and side (B) views of RF electrosurgical disc and washer probes (400 and 410 respectively). A single RF energy source is fed through each probe. The disc probe (400) is a circular probe with a circular active site (410). The washer probe (410) is a circular probe with a circular active site (412) with a hollow middle (414). Each of these probes may have a flat surface as shown in **Figures 20A** and **21A** or may be curved to conform to the curvature of the cornea. The disc probe may have a wire loop surface (415) as shown in **Figure 21C**.

Figures 20C, 21D and **21F** are side sectional views of the probes of **Figures 20A, 21A** and **21C**, respectively, for alternative embodiments. In **Figures 20C, 21D** and **21F**, the active sites are raised above the larger nonconductive areas. **Figures 20D, 21E** and **21G** are side sectional views of the probes of **Figures 20A, 21A** and **21C**, respectively, for alternative embodiments. In **Figures 20D, 21E** and **21G**, a small nonconductive portion immediately adjacent the active site is also raised above the larger nonconductive area.

Figures 22A and **B** illustrate the straight probe of **Figure 14D** and the disc probe of **Figure 20A**, respectively, in a sesquipolar configuration for removing tissue from a portion of the corneal mass (2200) near the center of the visual axis. Each probe includes a handle (2202) that is angled with respect to the contact end portion (2204) of the probe.

An active lead (2206) from an electrosurgical generator (2208) runs into the handle (2202) for connection to the active site (2210). The return electrode (2212) may be placed remotely on the body, e.g., onto a shaved area on the back of the patient's head. The return electrode (2212) is connected to the electrosurgical generator (2208) through a return lead (2214). Alternatively, the return electrode (2212) may be placed on the exterior of the cornea or onto the sclera or translimbal region (2216), as shown. The return electrode (2212) may simply rest in place or be held by a vacuum attachment cavity built into the electrode. Because of its significantly higher area as compared to the active tissue contacting site, the return electrode (2212) does not generate much heat. Those skilled in the art will understand that any of the probes described herein may use a handle, whether angled or not, for the convenience of the surgeon. Further, except for the bipolar probes, any of the probes of the invention may be arranged in the sesquipolar configuration of **Figures 22A** and **B**.

The above described probes are useful in the particular examples discussed below. The examples are illustrative only and are not intended to limit the scope of the invention.

The following examples are intended to describe a particular embodiment of the invention but are in no way intended to limit the invention in any manner.

Examples

Example 1 - The Correction of Astigmatism

In order to correct the astigmatic eye shown in **Figures 4A** and **4C** such that it becomes more similar to that shown in **Figures 4B** and **4D**, a process similar to that described above with regard to **Figures 3A-3D** is carried out. As shown in **Figures 23A** and **23C**, radial or circumferential partial depth incisions (500) are made in the periphery of the cornea. A lamellar separator is inserted to create a zone of separated lamellae (502) and (504) for the insertion of the electrical probe.

Two different approaches are possible to correct the astigmatic eye. In the first approach shown in **Figure 23C** the radial partial depth incisions and radial zone of separated lamellae will be formed beneath the astigmatic axis (506). Following separation of the lamellar tissue, one of the straight RF probes shown in **Figures 14-19 A** and **B** is

inserted through the partial depth incision (500). The probe is then activated to change the paracentral corneal volume (508), that is the volume near the center of the cornea, by ablation of the tissue under the figure-8-shaped astigmatism shown in **Figure 23A** and **23C**. The choice of RF probe design is dependent on the amount of tissue to be ablated. Once ablation is completed, the probe is withdrawn. Relief cuts on the anterior cornea may be necessary as described above to allow the surface of the cornea to conform to the underlying tissue removal. In this way, the steep astigmatic axis is flattened such that the cornea becomes reasonable symmetrical and spherical.

A second approach to the treatment of an astigmatic eye is to steepen the flat astigmatic axis as shown in **Figure 23A**. In this approach, the lamellar separation zone will be formed in the periphery of the cornea (502). The partial depth incision (500) is placed in the corneal periphery, beneath the astigmatic axis. Following separation of the lamellar tissue, one of the circular RF probes shown in **Figures 5, 6, 8, 9, 10,** and **11 A** and **B**, probes (200), (210), (220), (230), (240), (250) and (260) respectively, is inserted through the partial depth incision (500). The probe is then activated to change the volume by desiccation (probes (200), (210), (230), (240), (250) or (260)) or by ablation (probes (210), (240), (250), or (260)) of the tissue (501) under the flat axis of astigmatism axis (507) as shown in **Figure 23A**. Thus some probe configurations can be used either in the ablate or in the desiccation mode. Probe (200) is operated by inserting it into the lamellar tissue, activating it, deactivating it, and then removing it. Probes (210), (230), (240), (250), and (260) are operated by insertion into the lamellar tissue, activation, deactivation, rotation to a second position to be desiccated or ablated, activation, and then repeating this procedure until the desired tissue volume has been modified. Again, the choice of RF probe design is dependent on the amount of tissue to be ablated or desiccated. Once ablation or desiccation is completed, the probe is withdrawn. Relief cuts to the anterior cornea may be necessary as described above to allow the surface of the cornea to conform to the underlying tissue modification. In this way, the flat, astigmatic axis (507) is steepened such that the cornea becomes reasonably symmetrical and spherical.

An alternative to this second approach is to use a circular probe with an inwardly-directed contact end portion. Following separation of the lamellar tissue, one of the probes in **Figures 25-34** is inserted through the partial depth incision (500). The probes

can be used to change the volume by desiccation or ablation of the tissue (501) under the flat axis of astigmatism axis (507) as shown in **Figure 23A**. The probes are operated by insertion into the lamellar tissue, activation, deactivation, rotation to a second position to be desiccated or ablated, activation, and then repeating this procedure until the desired tissue volume has been modified. Again, the choice of RF probe design is dependent on the amount of tissue to be ablated or desiccated. Once ablation or desiccation is completed, the probe is withdrawn. Because astigmatic correction typically does not require tissue modification along a full 360 degrees, modification with one probe, rather than a complementary pair, may be sufficient. Again, relief cuts on the anterior corneal surface may be necessary as described above to allow the surface of the cornea to conform to the underlying tissue removal.

Example 2 - The Correction of Hyperopia

In order to correct hyperopia a process similar to that described above with regard to **Figures 3A-3D** is carried out. As shown in **Figures 23B, 23D** and **23E**, radial or circumferential partial depth incisions (510) are made in the periphery of the cornea. A lamellar separator is inserted to create a lamellar pathway (512) for the insertion of the electrical probe.

Two different approaches are possible to correct the hyperopic eye. In the first approach, shown in **Figure 23B**, partial depth incisions (510) are made in the peripheral cornea and a circumferential lamellar separation zone (512) will be formed beneath the corneal surface.

A circular intrastromal channel may first be made using the apparatus of US Patent No. 5,403,335, issued to Loomas *et al.*, and assigned to the assignee of the present invention. That patent is incorporated by reference herein in its entirety. During the creation of the channel, the support base of **Figures 24D-F** may be substituted for the support base of the Loomas patent so as to provide a sesquipolar return electrode for use during the later stage of tissue volume reduction.

Following separation of the lamellar tissue, one of the circular probes or one of the circular probes with an inwardly-directed contact end portion described herein is inserted through the partial depth incision (512). In particular, the assembly of **Figures**

24A-D may be employed. If using the latter type of probe, the radial inwardly-directed contact end portion is first inserted without using the support base shown in **Figure 24D**. The support base is then slipped over the barrel, or alternatively, the procedure is performed freehand. For the former probe type, the base may be in place over the eye during initial insertion. Once the guide is in place, the barrel is rotated and the rest of the circular probe enters the cornea. The probe is then activated to change the volume by ablation or desiccation of the tissue (514) in the channel. This procedure may also be employed to correct myopia or astigmatism, using the probes and motions appropriate for those corrections. The choice of RF probe design is dependent on the amount and location of tissue to be ablated or desiccated.

Circular probes (210), (220), (230), (240), (250) and (260) will allow for desiccation of the channel. Circular probe (220) is operated by inserting it into the lamellar tissue, activating it, deactivating it, and then removing it. The other circular probes are operated by inserting them into the lamellar tissue, activating, deactivating, rotating to a second position to be ablated, activating, deactivating and repeating this process until the entire channel is desiccated, and then removing it. Circular probes (210), (240), (250) and (260) will allow for ablation of the channel. The probes are operated by insertion into the lamellar tissue, activation, deactivation, rotation to a second position to be ablated, activation, and repeating until the entire channel is ablated, followed by removal of the probe. Circular probes (250) and (260) can also be operated by complete insertion into the lamellar tissue, activation, deactivation, pulling partially back out of the tissue to a second position to be ablated, activation, deactivation and repetition of this process until the entire channel is ablated, followed by removal of the probe. Again, relief cuts in the anterior of the cornea may be necessary as described above to allow the surface of the cornea to conform to the underlying tissue removal. In this way, the central corneal surface is steepened such that the cornea curvature is improved.

Circular probes with inwardly-directed contact end portions (265), (284), (289), (291), and (298), for example, will also allow for either desiccation or ablation of the channel to correct for hyperopia. The other probes may also be used if modified to remove an annulus of tissue for hyperopic correction. The probes are operated using a clockwise/counterclockwise set. First, one probe is inserted into the lamellar tissue,

activated, deactivated, rotated to a second position to be ablated or desiccated, activated, and repeated until half the circular channel is ablated or desiccated, followed by removal of the probe. The complementary probe is then inserted into the lamellar tissue, activated, deactivated, rotated to a second position in the opposite direction than that of the first probe to be ablated or desiccated, activated, and repeated until the second half of the circular channel is ablated or desiccated, followed by removal of the probe. Again, relief cuts in the anterior of the cornea may be necessary as described above to allow the surface of the cornea to conform to the underlying tissue removal. In this way, the central corneal surface is steepened such that the cornea curvature is improved.

A second approach to the treatment of a hyperopic eye is to use a straight RF probe. In this second approach 2 or more partial depth incisions (510) are made in the periphery and 2 or more radial lamellar separation zones are formed as shown in **Figures 23D** and **23E**. Following separation of the lamellar tissue, one of the straight RF probes shown in **Figures 12-19 A** and **B** is inserted through each partial depth incision (510) in the lamellar separation zones (512) and (514). The probe is then activated to change the volume by ablation or desiccation of the tissue in the channel. The choice of RF probe design is dependent on the amount of tissue to be ablated or desiccated. Probes (300), (310), (320), (330), (340), (350), (360) and (370) will allow for desiccation of the channel. Probes (300) and (310) are operated by insertion into the lamellar tissue, activation, deactivation, and then removal. Probes (320), (330), (340), (350), (360) and (370) are operated by inserting into the lamellar tissue, activating, deactivating, moving to a second position to be ablated, activating, deactivating and repeating this process until enough of the channel is desiccated, and then removing the probe. In this way the tissue desiccated can either form a continuous path (516) or can be interrupted points along the radial lamellar separation channel (518). Probes (320)-(370) will allow for ablation of corneal volume inside the radial lamellar separation channel. Probes (320), (340), (350), (360) and (370) are operated by insertion into the lamellar tissue, activation, deactivation, moving it further into the tissue to a second position to be ablated, activation, and repeating until the entire channel is ablated, and then removal. The same probes can also be operated by complete insertion into the lamellar separation channel, activation, deactivation, pulling back out of the tissue channel to a second position to be ablated, activation, deactivation

and repetition of the process until the enough of the channel is ablated, followed by removal of the probe. Again, relief cuts may be necessary in the anterior cornea as described above to allow the surface of the cornea to conform to the underlying tissue removal. In this way, the corneal surface is steepened centrally such that the corneal curvature is improved.

Example 3 - The Correction of Myopia

In order to correct myopia the process similar to that described above with regard to **Figures 3A-3D** is carried out. As shown in **Figures 23F** and **23G**, radial or circumferential partial depth incisions (520) are made in the periphery of the cornea. A lamellar separator is inserted to create a radial lamellar separation channel (522) toward the center of the pupil for the insertion of the electrical probe.

For correction of myopia, the lamellar path (522) will be formed under or near the central or paracentral portion of the cornea. Following separation of the lamellar tissue, one of the straight RF probes shown in **Figures 14-19 A** and **B** or the disc or washer probes shown in **Figures 20-21 A** and **B** is inserted through the peripheral partial depth incision (520) into the lamellar separation channel (522). The probe is then activated to change the volume by ablation of the tissue in the channel, the volume change (524) resulting from the use of the disc-shaped probe (400) is shown in **Figure 23F** and volume change (526) resulting from the use of the washer-shaped probe (410) is shown in **Figure 23G**. The choice of RF probe design is dependent on the amount of tissue to be ablated. Probes (320)-(370) will allow for ablation of the channel. The probes are operated by insertion into the lamellar tissue, activation, deactivation, advancing the probe into the channel to a second position to be ablated, activation, deactivation, repeating the process until the entire channel is ablated, and then the probe is removed. The probes can also be operated by complete insertion into the lamellar separation channel, activation, deactivation, pulling out of the channel to a second position to be ablated, activation, deactivation and repeating the process until the entire channel is ablated, and then the process is removed. Probes (400) and (410) are operated by insertion into the lamellar separation channel (522), activation, deactivation and removal from the channel. Again, relief cuts in the anterior cornea may be necessary as described above to allow the surface

of the cornea to conform to the underlying tissue removal. In this way, the corneal surface in the central corneal area is flattened such that the corneal curvature is improved.

A second approach to the treatment of a myopic eye is to use a complementary pair of circular probes with inwardly-directed contact end portions. As with use of the straight probes, a lamellar separator is first inserted to create a radial lamellar separation channel toward the center of the pupil for the insertion of the electrical probe. Following separation of the lamellar tissue, probe (270), (275), (280), (500), or (505), for example, is inserted through the peripheral partial depth incision into the lamellar separation channel. Other probes may be used if modified to remove tissue from a central corneal area to correct myopia. The probe is operated by activation, deactivation, advancement of the probe into the channel to a second position to be ablated or desiccated, activation, deactivation, and repeating the process until the radial inwardly-directed contact end portion has rotated 180 degrees and half the radial channel is ablated or desiccated. The probe is then removed and the complementary probe is inserted and operated in the same manner as the first probe, but rotated 180 degrees in the opposite direction so that the entire radial channel is ablated or desiccated as shown in **Figure 23F**. Again, relief cuts in the anterior cornea may be necessary as described above to allow the surface of the cornea to conform to the underlying tissue removal. In this way, the corneal surface in the central corneal area is flattened such that the corneal curvature is improved.

The foregoing examples of procedures and devices according to the present invention are only representative and are not meant to be in any manner limiting. Other embodiments, areas of application, methods of use of the present invention, within the scope of the claims appended hereto, will be evident to those skilled in this art. Other embodiments of the procedures without the scope of the claims but within the spirit of invention described herein are considered to be equivalent to those procedures and devices claimed.

WHAT IS CLAIMED IS:

1. An electrosurgical probe for insertion into a corneal mass comprising:

a housing having a support portion and a contact end;

at least one active tissue contact site comprising a conductive material and disposed at the contact end of the housing, each of the at least one active site having a height, the height being selectively adjustable.

2. The electrosurgical probe of claim 1, wherein the height of the at least one active site is adjustable in response to pressure applied to the active site.

3. The electrosurgical probe of claim 2, the at least one active site comprising a flexible conductive material, the support portion including a passage for operably coupling the flexible material to a pressure supply, wherein the height of the active site varies in response to changes in pressure from the pressure supply.

4. The electrosurgical probe of claim 1, further comprising:

a moveable piston disposed within the contact end of the housing and having the at least one active site attached thereon, wherein the movable piston moves to adjust the height of the at least one active site; and

an actuator for moving the piston to change the height of the at least one active site.

5. The electrosurgical probe of claim 4, wherein the actuator includes a pressure chamber located within the contact end and wherein the moveable piston moves in response to changes in pressure within the pressure chamber.

6. The electrosurgical probe of claim 4, further comprising a spring for biasing the movable piston in a direction away from the at least one active site.

7. The electrosurgical probe of claim 4, wherein the at least one active site is located on an exterior surface of the moveable piston.

8. The electrosurgical probe of claim 7, wherein at least a portion of the exterior surface of the movable piston is rounded.

9. The electrosurgical probe of claim 4, wherein the at least one active site is removably attached to the movable piston.

10. The electrosurgical probe of claim 1, further comprising a pressure chamber located within the contact end of the housing and an expandable material expandable in response to pressure changes within the pressure chamber, wherein the at least one active site is attached to the expandable material.

11. The electrosurgical probe of claim 10, wherein the at least one active site comprises a conductive layer attached to the expandable material by an adhesive material.

12. The electrosurgical probe of claim 11, wherein the at least one active site comprises a layer of conductive material sputter deposited onto the expandable material.

13. The electrosurgical probe of claim 12, wherein the at least one active site is arranged to allow expansion of said expandable material.

14. The electrosurgical probe of claim 1, wherein the contact end of the housing comprises a nonconductive material.

15. The electrosurgical probe of claim 1, wherein the at least one active site is electrically coupled to a radio frequency energy line for delivery of radio frequency energy to the at least one active site.

16. The electrosurgical probe of claim 1, further comprising a thermal expansion element disposed in the contact end of the housing, wherein thermal expansion or compression of the element is controllable to selectively adjust the height of the at least one active site.

17. An electrosurgical system for introduction into a corneal mass comprising:

a probe having a housing including a contact end and a support;

at least one active surface area comprising a conductive material and disposed at the contact end of the housing, each of the at least one active area having a height, the height being selectively adjustable;

a sensor operably coupled to at least one of the contact end and the active area for generating one or more signals in response to a parameter; and

a microprocessor for receiving the one or more signals from the sensor and for generating an output indicative of the height of the active area.

18. The electrosurgical system of claim 17, wherein the microprocessor includes an active feedback loop for maintaining the active site at a predetermined height.

19. The electrosurgical system of claim 17, wherein the microprocessor includes a look-up table for corresponding the one or more signals to the height of the at least one active area.

20. A method for altering the shape of the cornea, comprising:

inserting an electrosurgical probe into an intrastromal channel, the probe comprising a conductive active region; and

applying a current to the electrosurgical probe to activate the active region of the electrosurgical probe to selectively change the volume of the cornea by removing and/or shrinking portions thereof.

21. The method of claim 20, wherein applying a current to the electrosurgical probe delivers radio frequency energy to the conductive active region.

22. The method of claim 20, wherein the radio frequency energy is delivered is pulsed or continuous, non-pulsed.

23. The method of claim 20, further comprising removing the electrosurgical probe from the cornea.

24. The method of claim 20, further comprising forming a corneal surface incision, wherein said electrosurgical probe is inserted into the corneal tissue though one of the at least one corneal surface incision.

25. The method of claim 20, further comprising forming one or more corneal surface relief incisions.

26. The method of claim 20, wherein activating the electrosurgical probe causes vaporization of the regions of the cornea adjacent to the active region of the probe.

27. The method of claim 20, wherein activating the electrosurgical probe causes desiccation such that the region of the cornea adjacent to the active region of the probe shrinks or necroses.

28. The method of claim 20, wherein the electrosurgical probe has a desiccation mode and an ablation mode, wherein activation in the desiccation mode causes desiccation such that the region of the cornea adjacent to the active region of the probe shrinks or necroses and wherein activation in the ablation mode causes causes vaporization of the regions of the cornea adjacent to the active region of the probe.

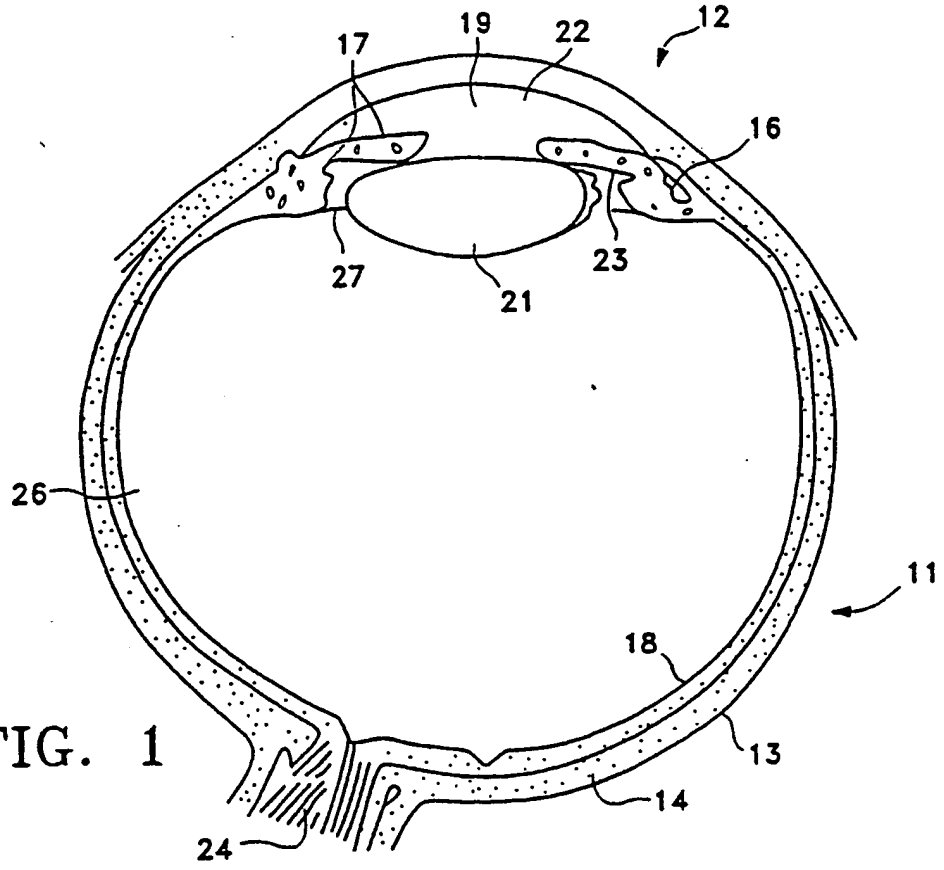


FIG. 1

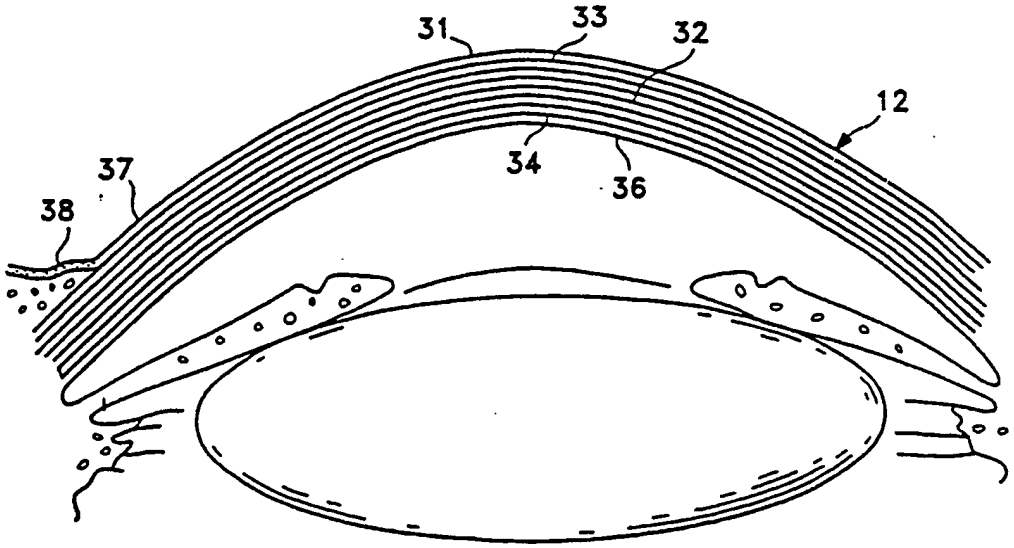


FIG. 2

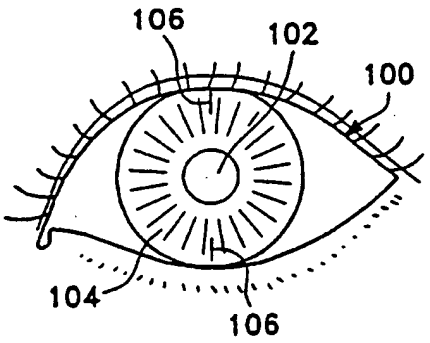


Fig. 3A

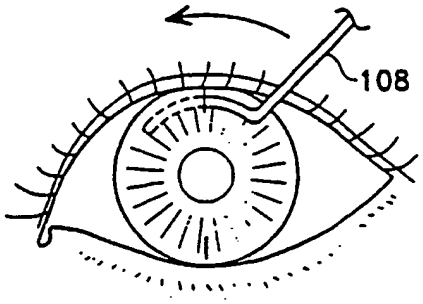


Fig. 3B

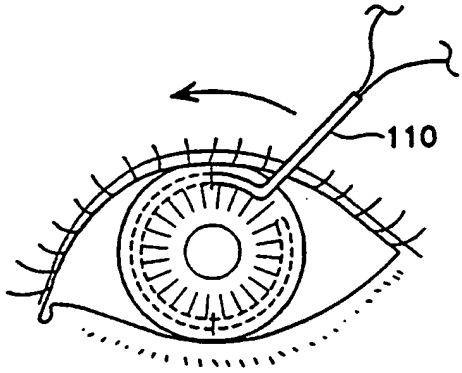


Fig. 3C

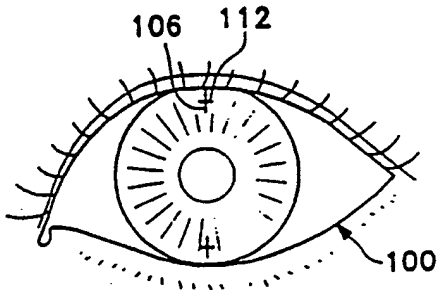


Fig. 3D

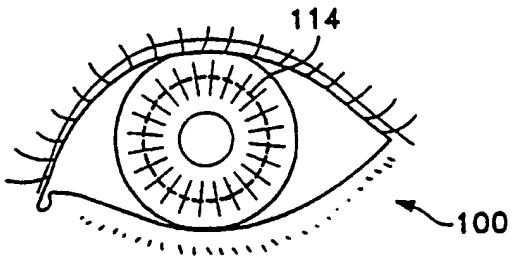


Fig. 3E

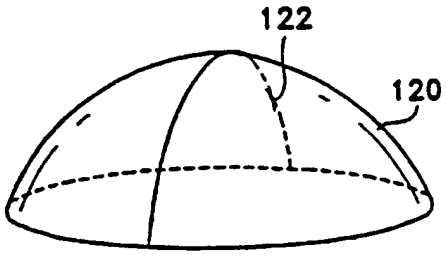


Fig. 4A

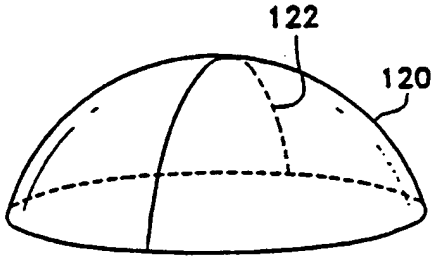


Fig. 4B

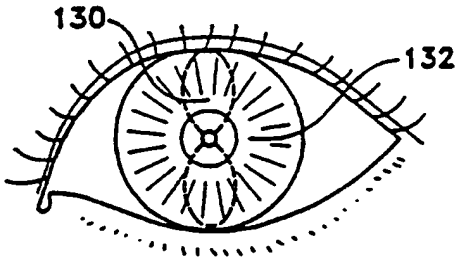


Fig. 4C

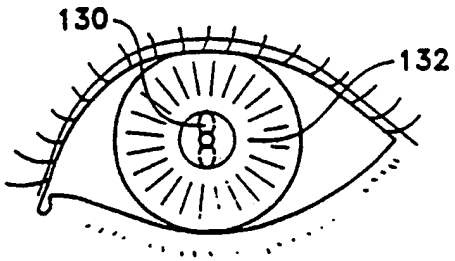


Fig. 4D

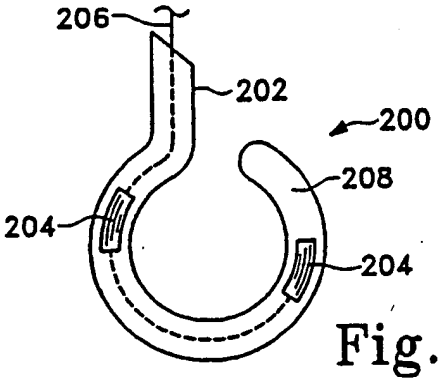


Fig. 5A

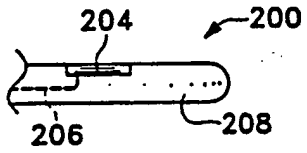


Fig. 5B

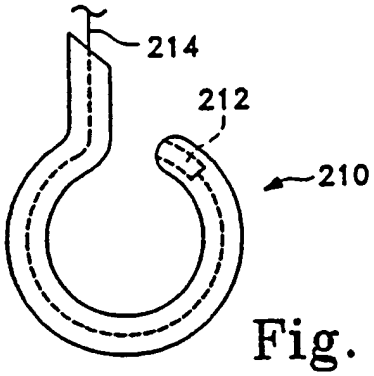


Fig. 6A

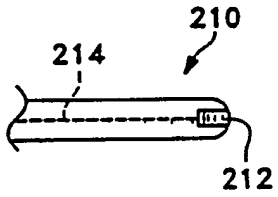


Fig. 6B

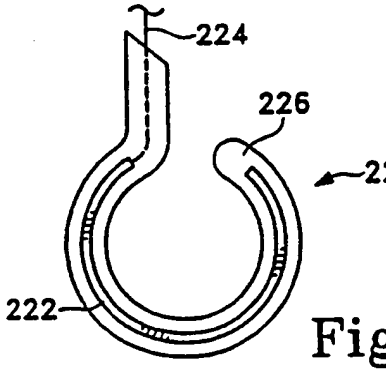


Fig. 7A

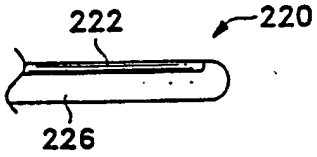


Fig. 7B

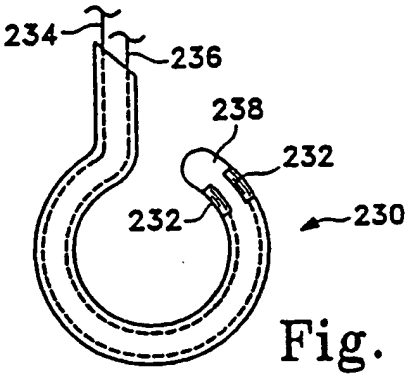


Fig. 8A

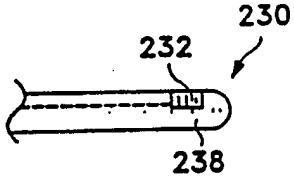


Fig. 8B

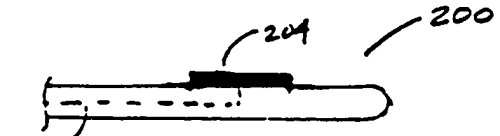


Figure 5C

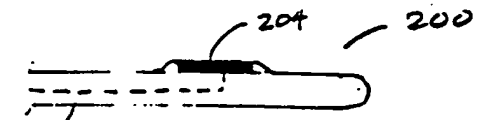


Figure 5D

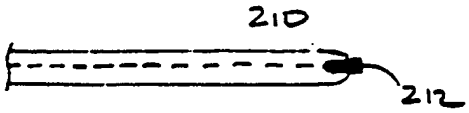


Figure 6C

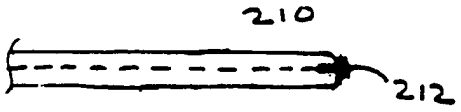


Figure 6D

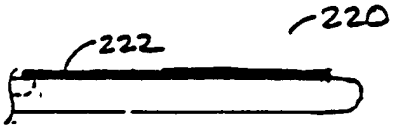
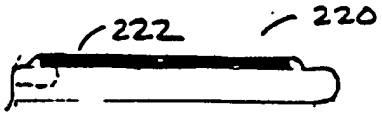


Figure 7C



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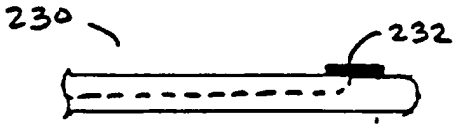
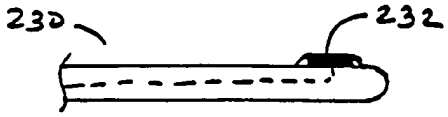


Figure 8C



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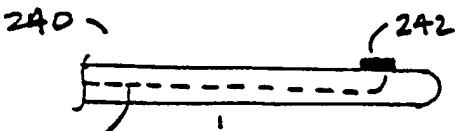


Figure 9C

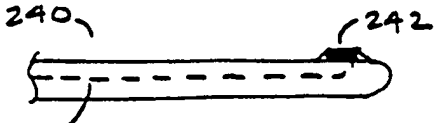


Figure 9D

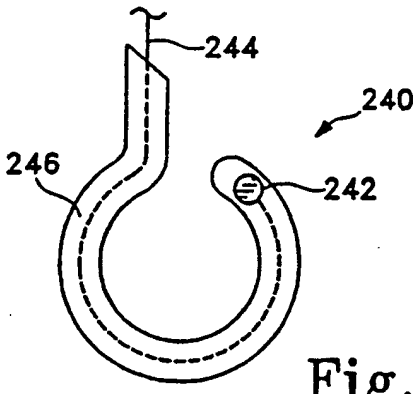


Fig. 9A

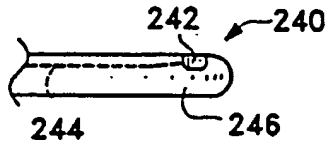


Fig. 9B

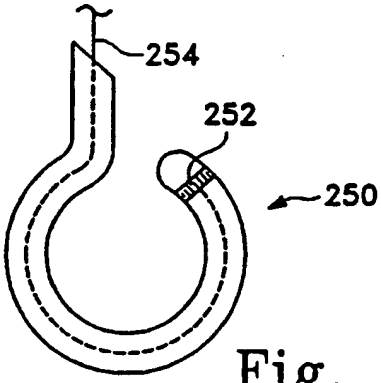


Fig. 10A

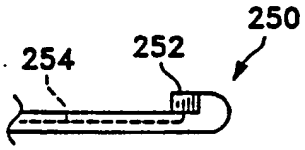


Fig. 10B

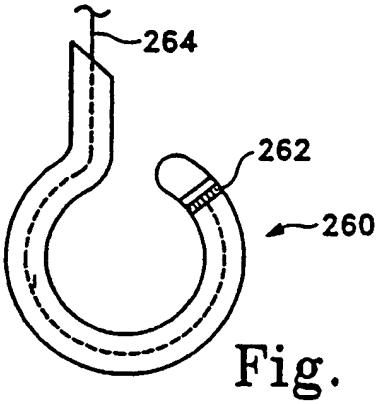


Fig. 11A

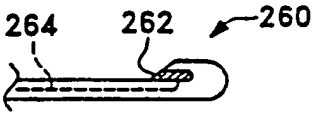


Fig. 11B

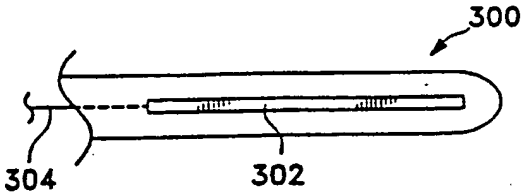


Fig. 12A

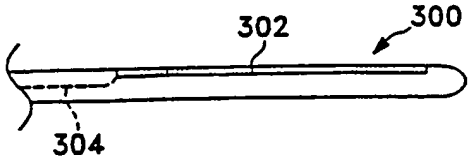


Fig. 12B

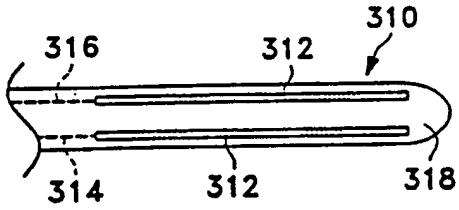


Fig. 13A

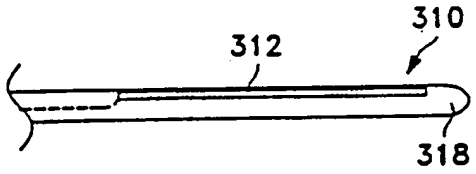


Fig. 13B

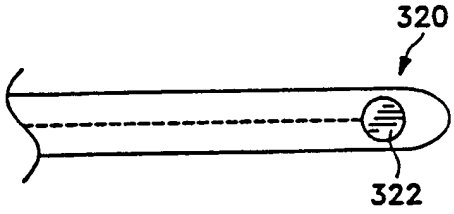


Fig. 14A

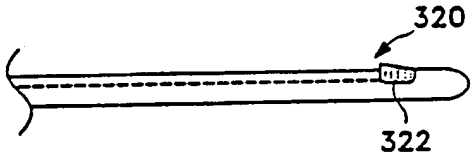


Fig. 14B

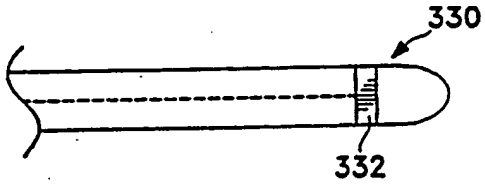


Fig. 15A

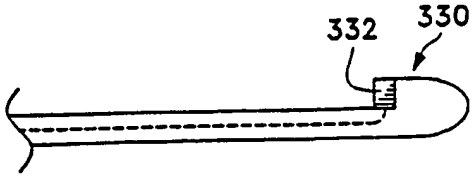


Fig. 15B

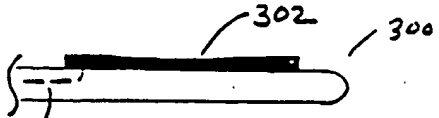
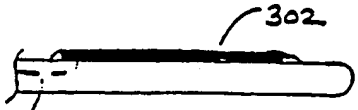


Figure 12C



side

Figure 12D

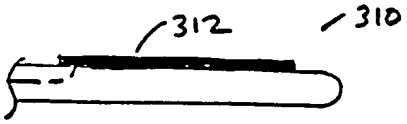


Figure 13C

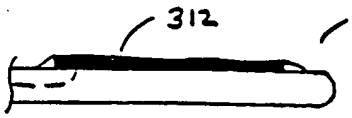


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Figure 13D

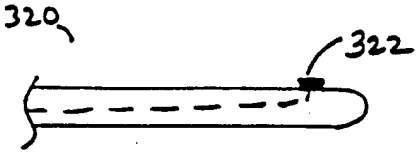

Figure 14C

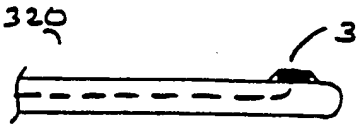

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Figure 14D

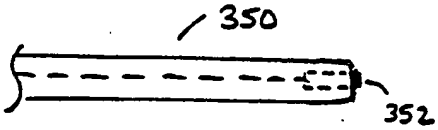
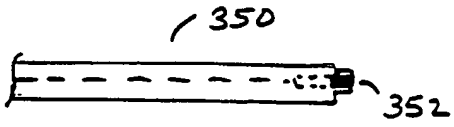


Figure 17C



top

Figure 17D

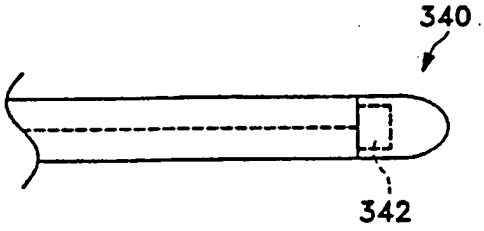


Fig. 16A

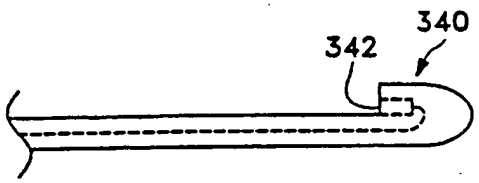


Fig. 16B

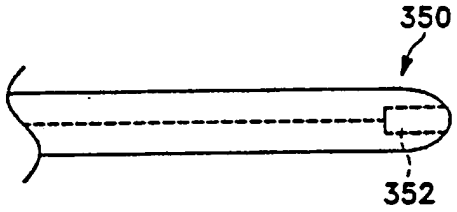


Fig. 17A

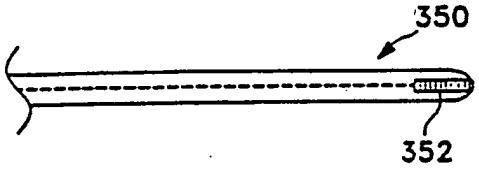


Fig. 17B

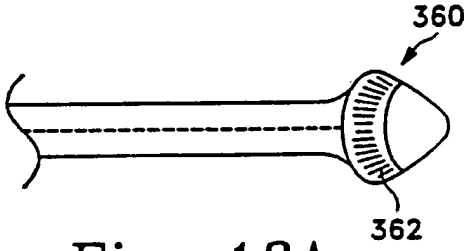


Fig. 18A

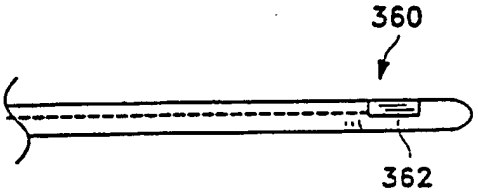


Fig. 18B

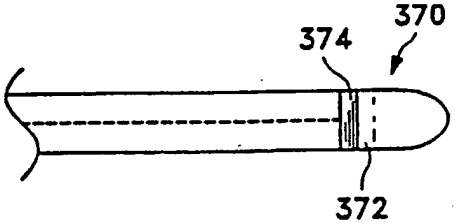


Fig. 19A

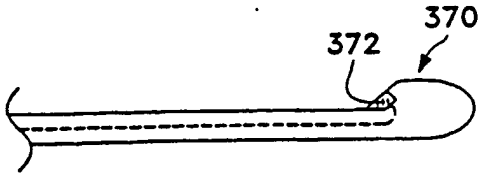


Fig. 19B

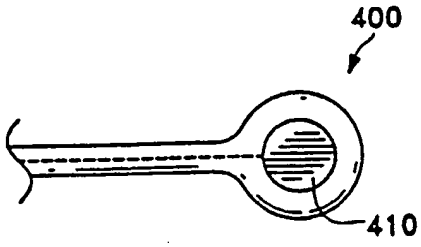


Fig. 20A

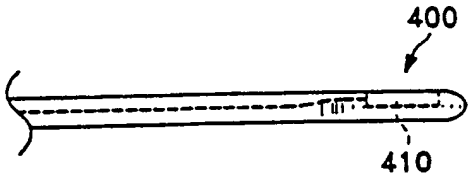


Fig. 20B

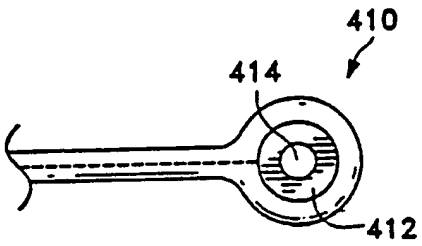


Fig. 21A

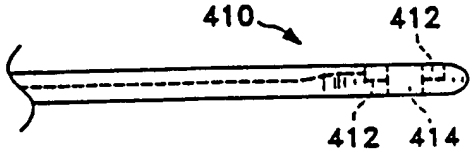


Fig. 21B

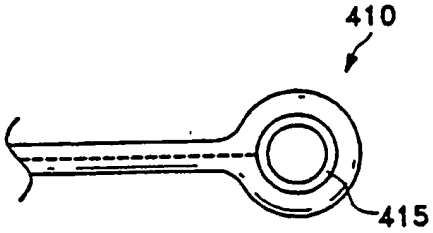


Fig. 21C

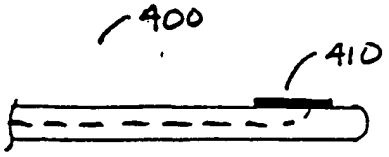


Figure 20C

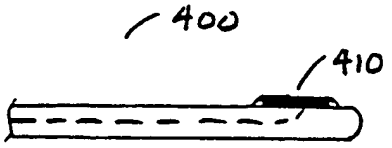


Figure 20D

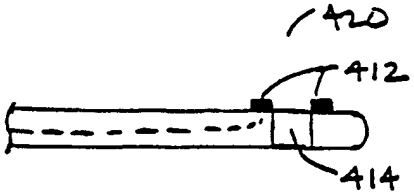


Figure 21D

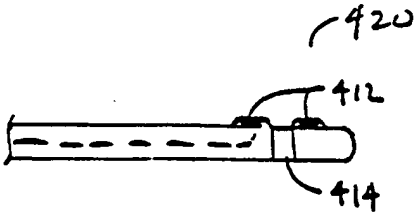


Figure 21E

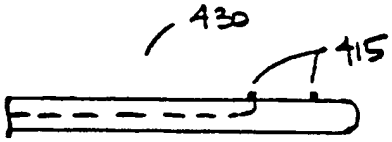


Figure 21F

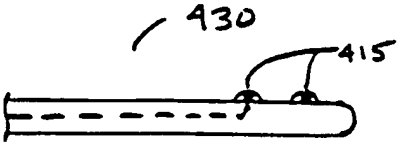


Figure 21G

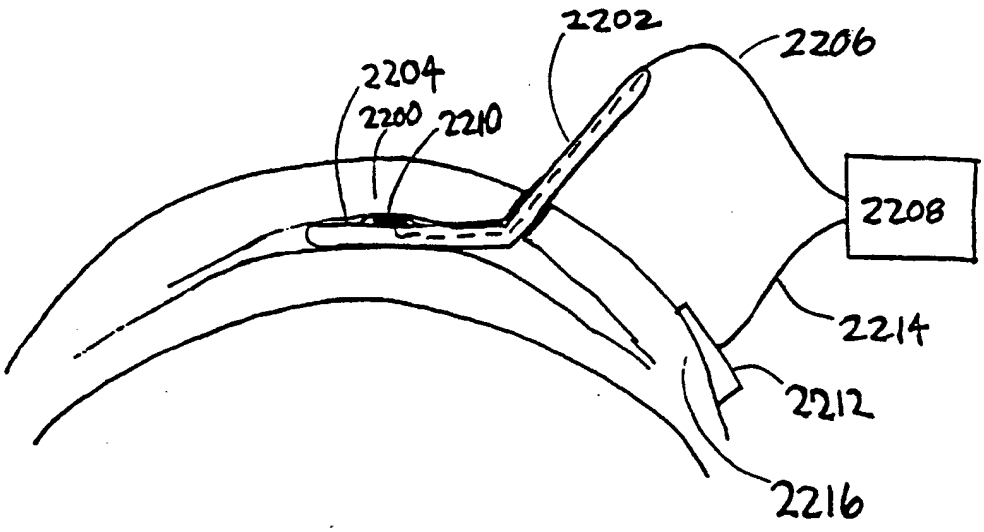


Figure 22A

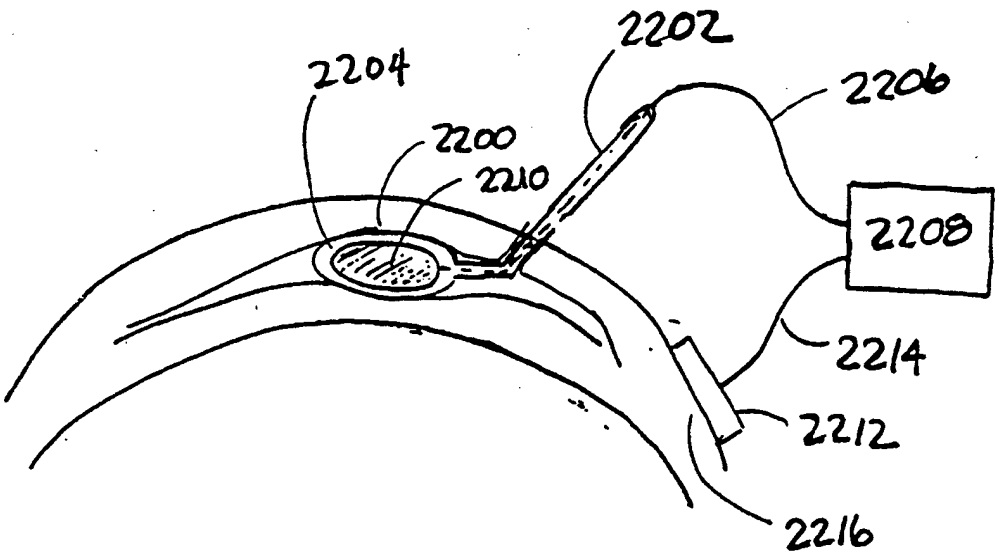


Figure 22B

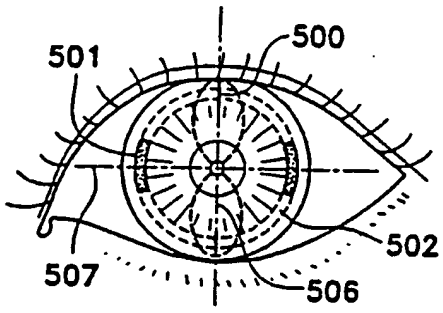


Fig. 23A

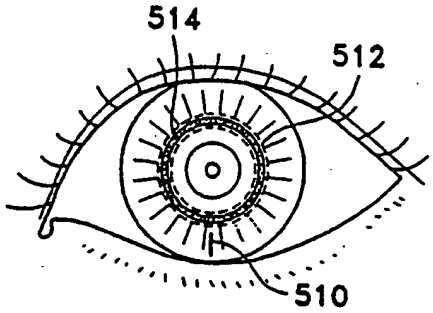


Fig. 23B

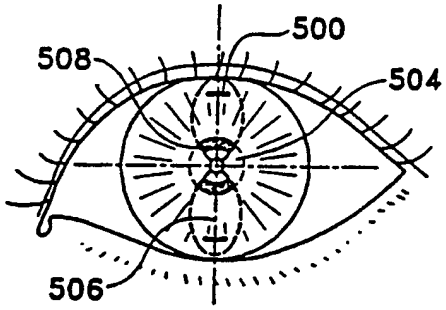


Fig. 23C

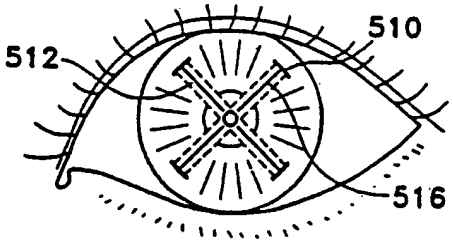


Fig. 23D

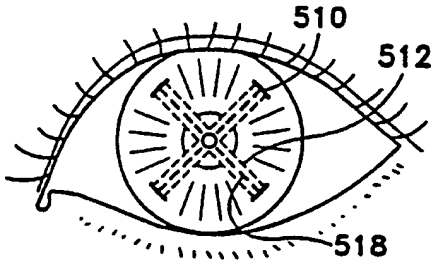


Fig. 23E

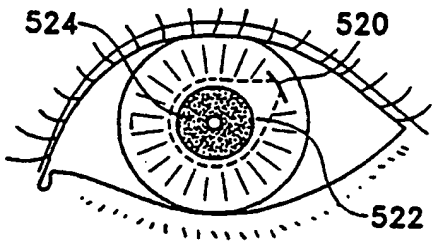


Fig. 23F

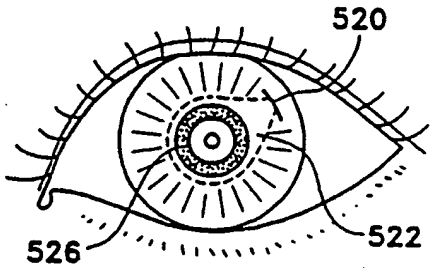


Fig. 23G

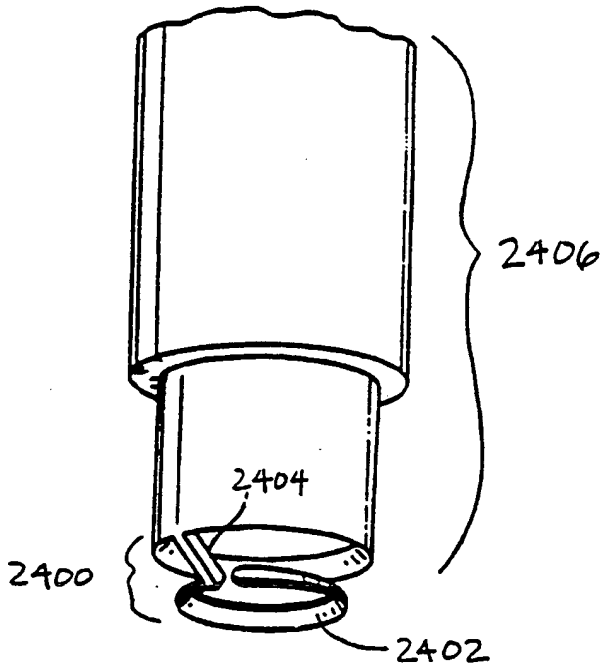


Figure 24A

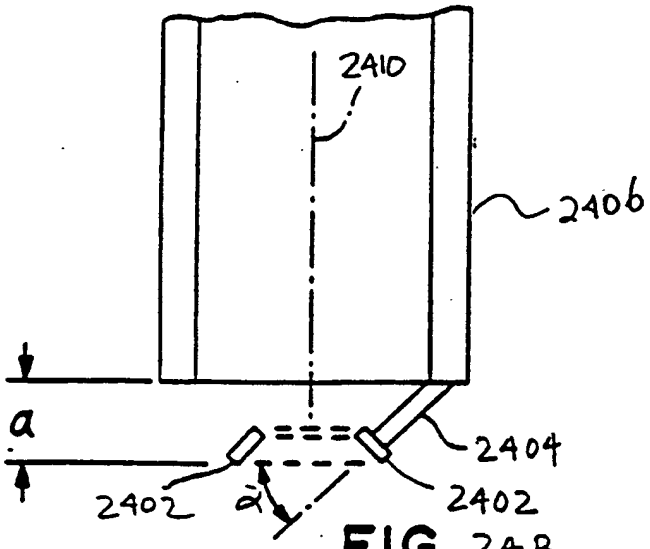


FIG. 24B

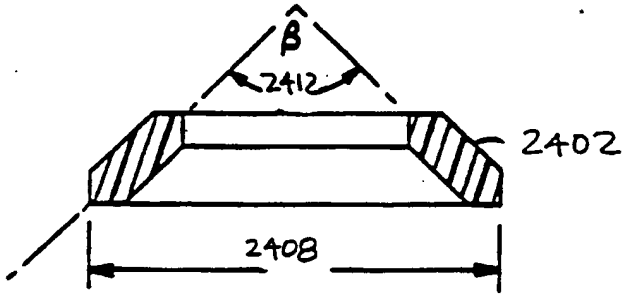


FIG. 24C

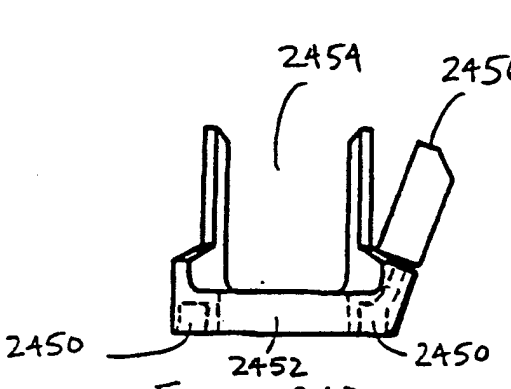


Figure 24D

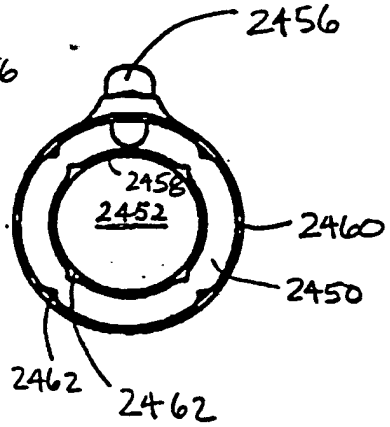


Figure 24E

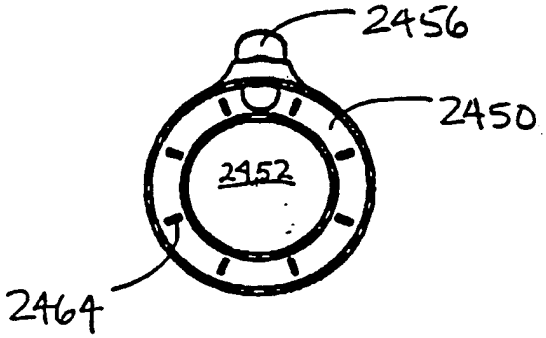


Figure 24F

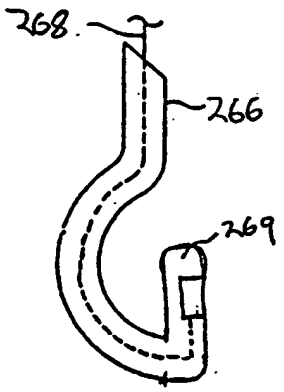


Fig. 25A

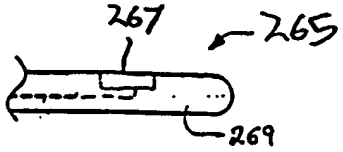


Fig. 25B

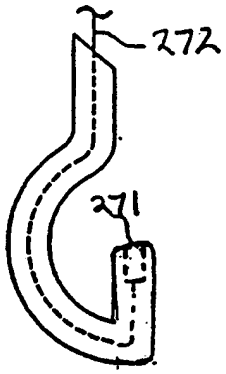


Fig. 26A

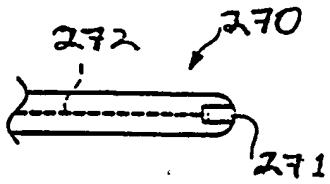


Fig. 26 B

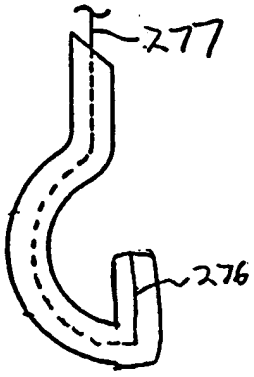


Fig. 27A

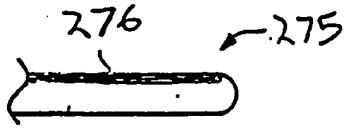


Fig. 27 B

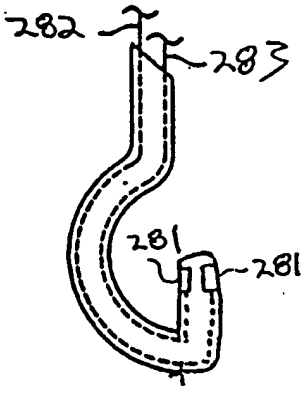


Fig. 28A

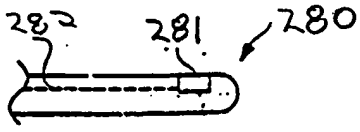


Fig. 28B

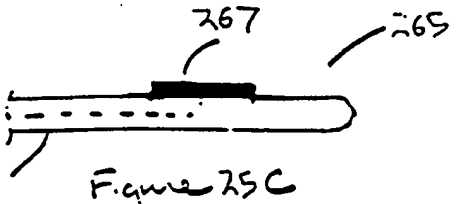


Figure 25C

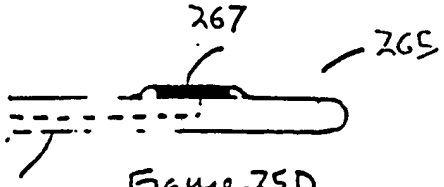


Figure 25D

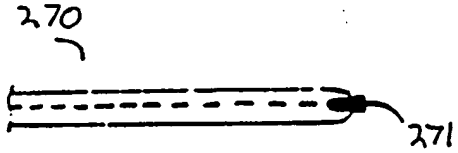


Figure 26C

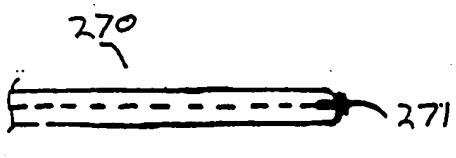


Figure 26D

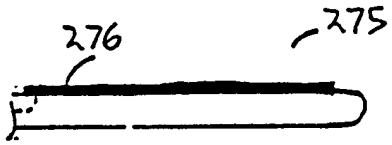


Figure 27C

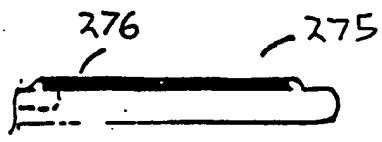


Figure 27D

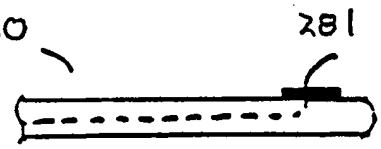


Figure 28C

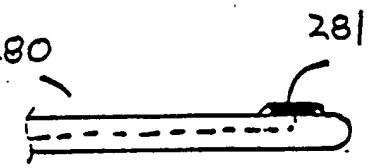


Figure 28D

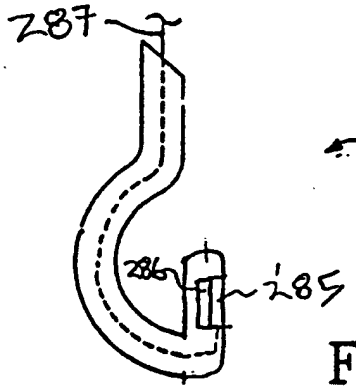


Fig.29A

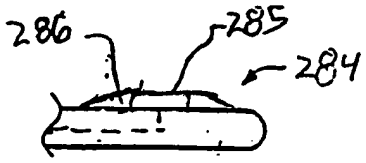


Fig.29B

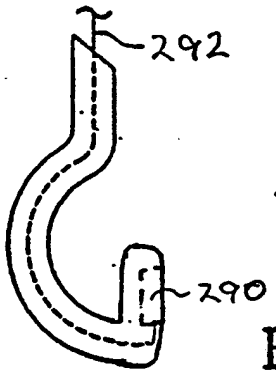


Fig.30A

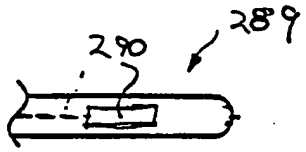


Fig.30B

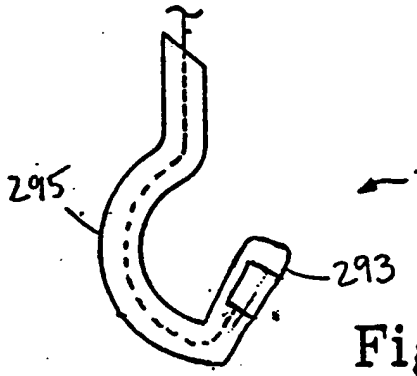


Fig.31A

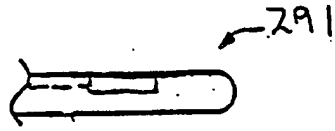


Fig.31B

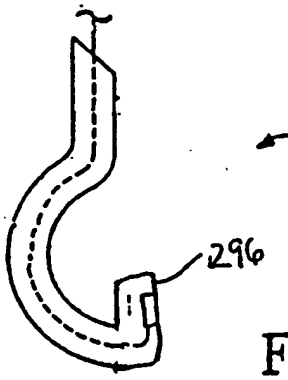


Fig.32A

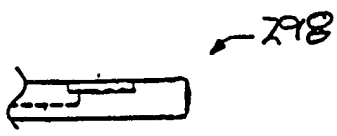


Fig.32B

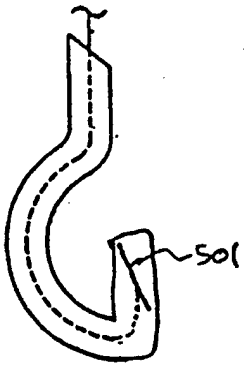


Fig.33A

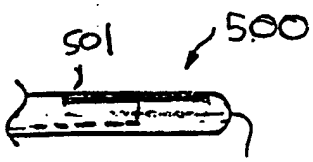


Fig.33B

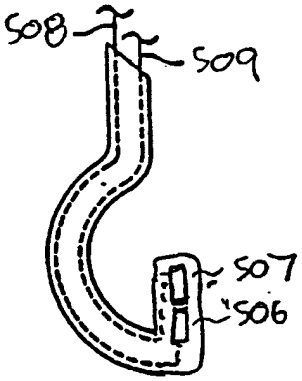


Fig.34A

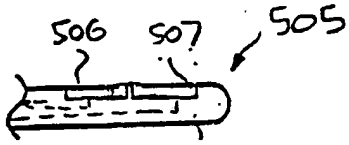


Fig.34B

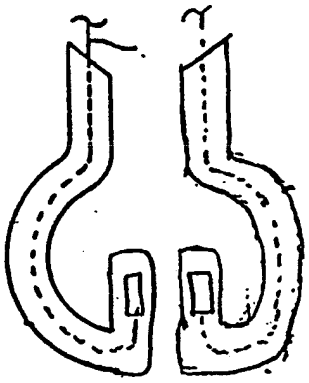


Fig. 35

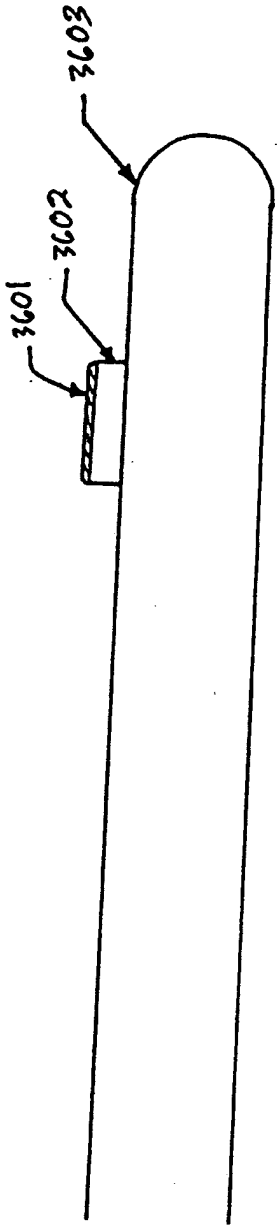


Figure 36A

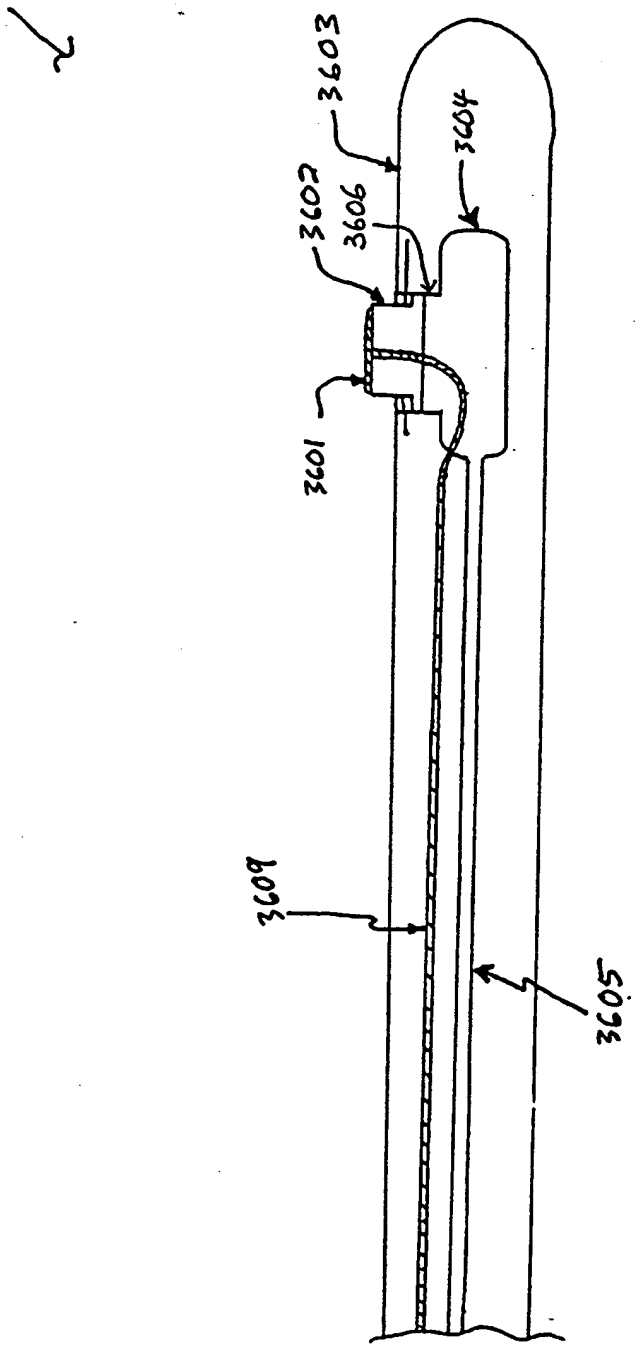


FIG. 36B

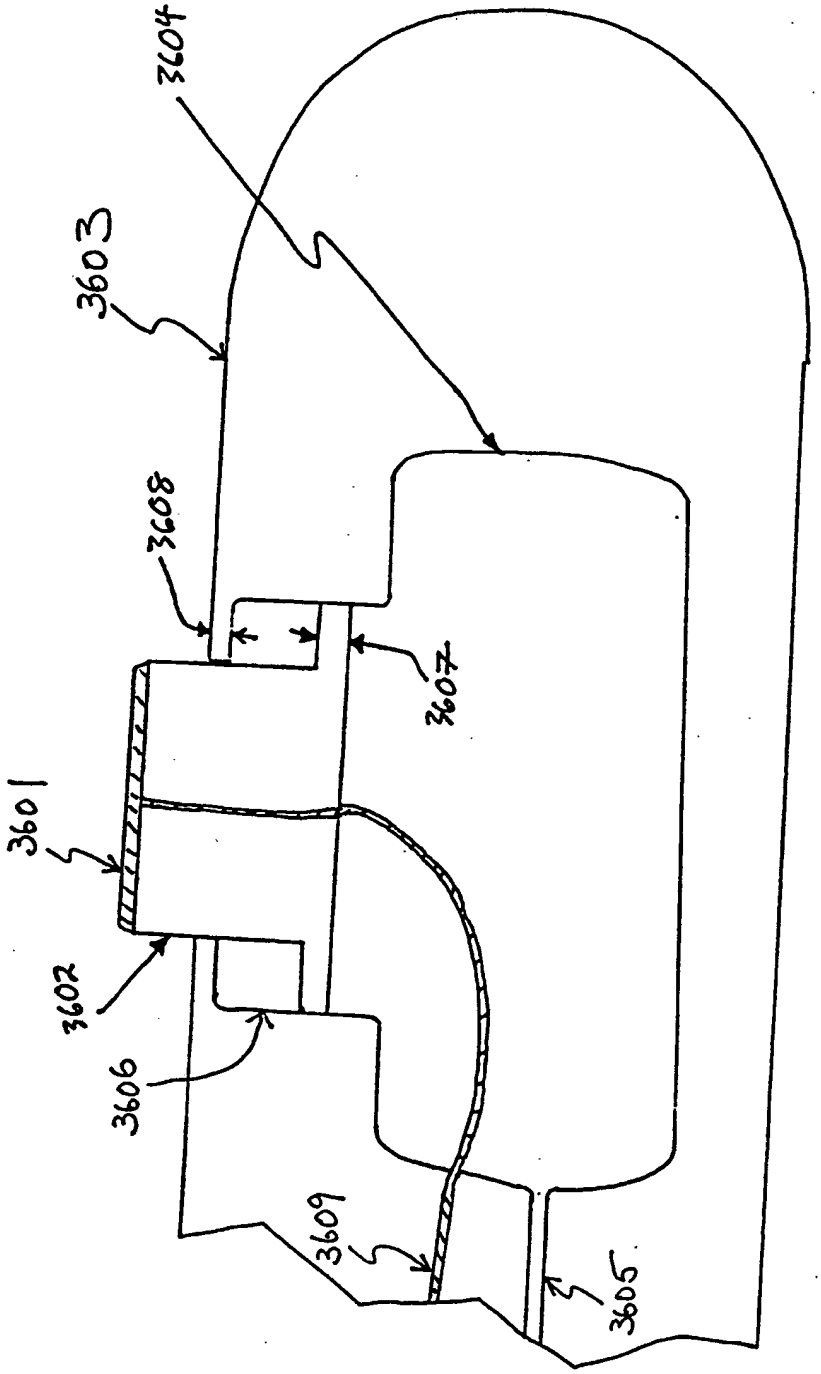


Figure 36C

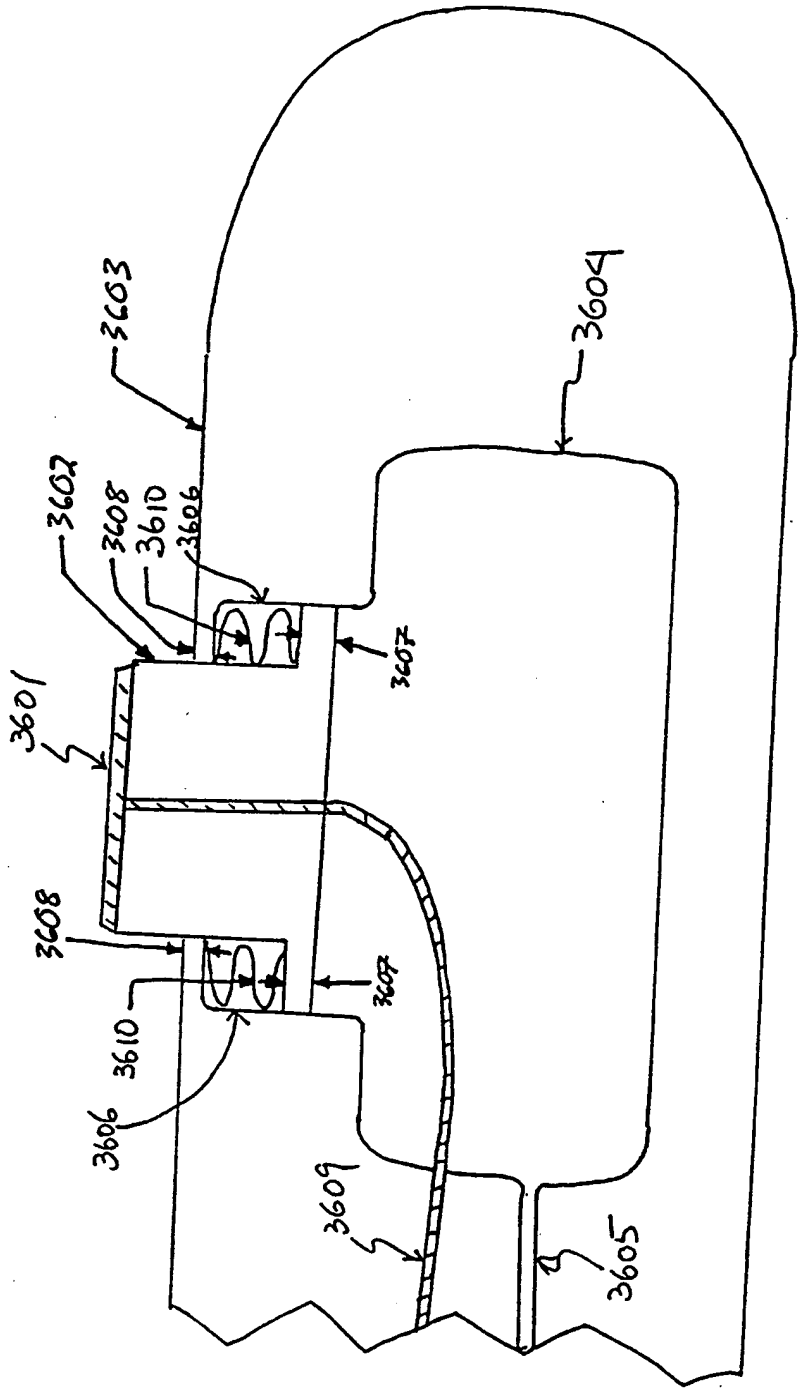

3603
3604
3602
3608
3610
3606
3607
3601
3608
3607
3610
3606
3609
3605

Figure 36D

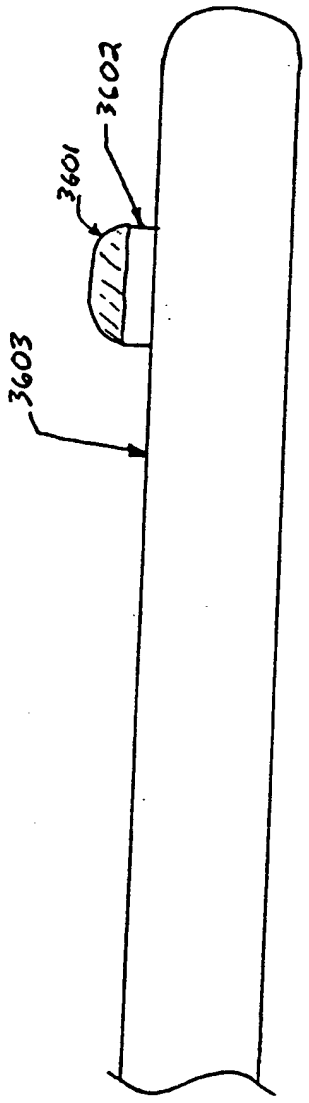
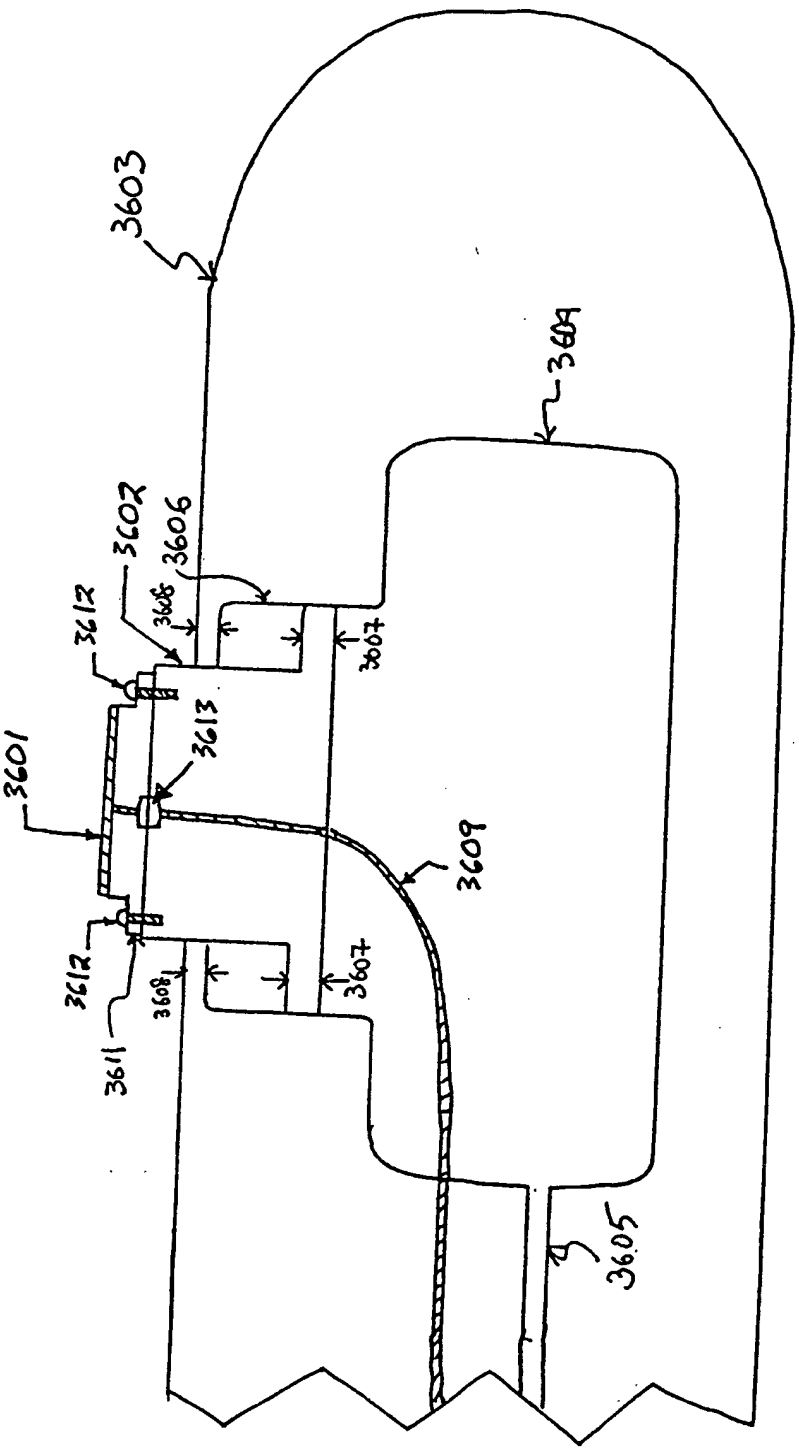


Figure 36E


3603
3604
3602
3606
3612
3608
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3613
3601
3609
3612
3608
3607
3611
3605

Figure 36F

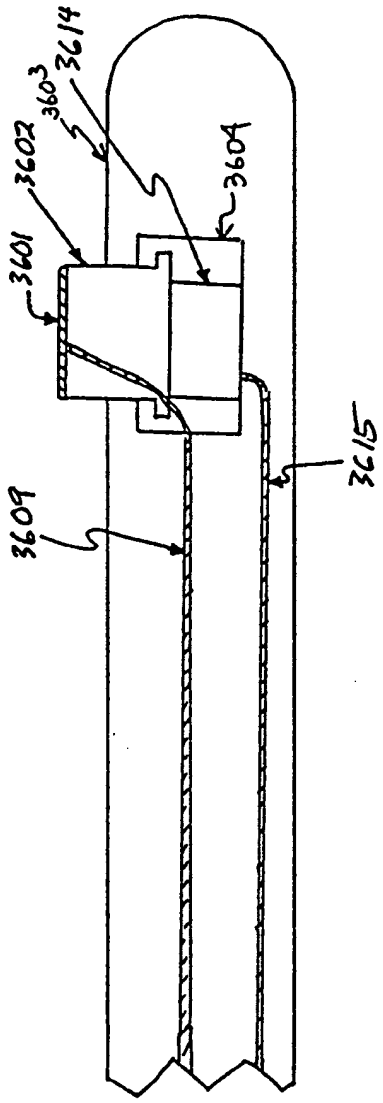

Figure 36G

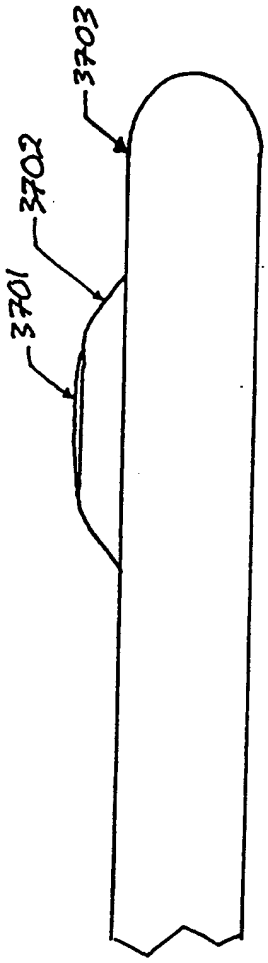

Figure 37A

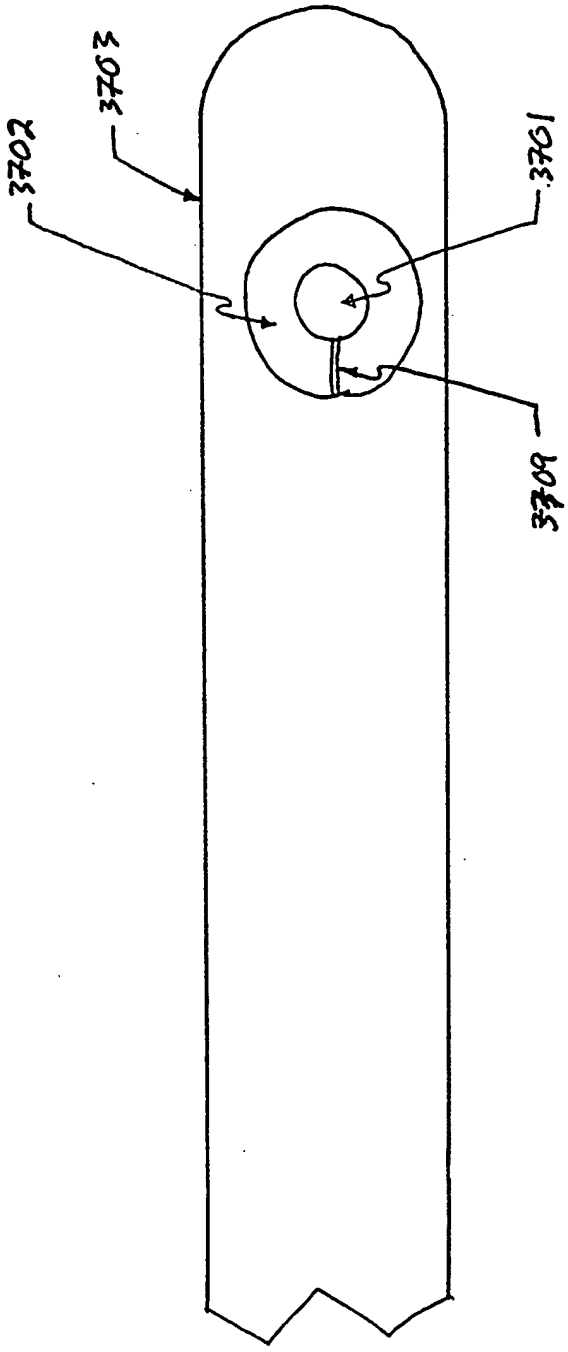

Figure 37B

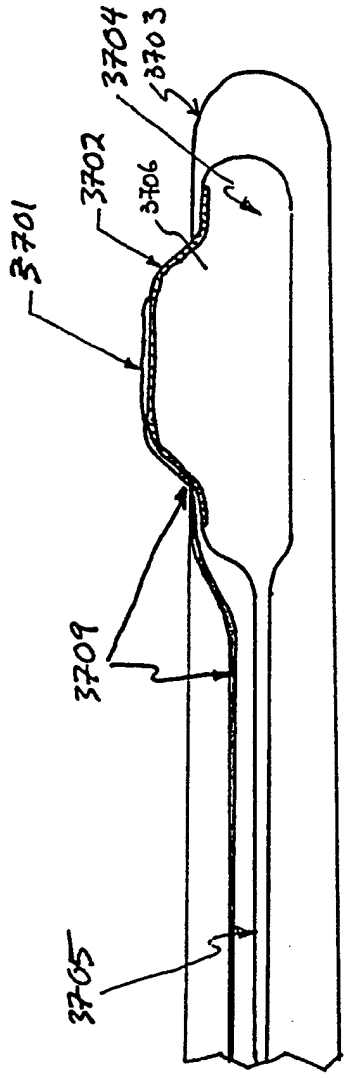

Figure 37 C

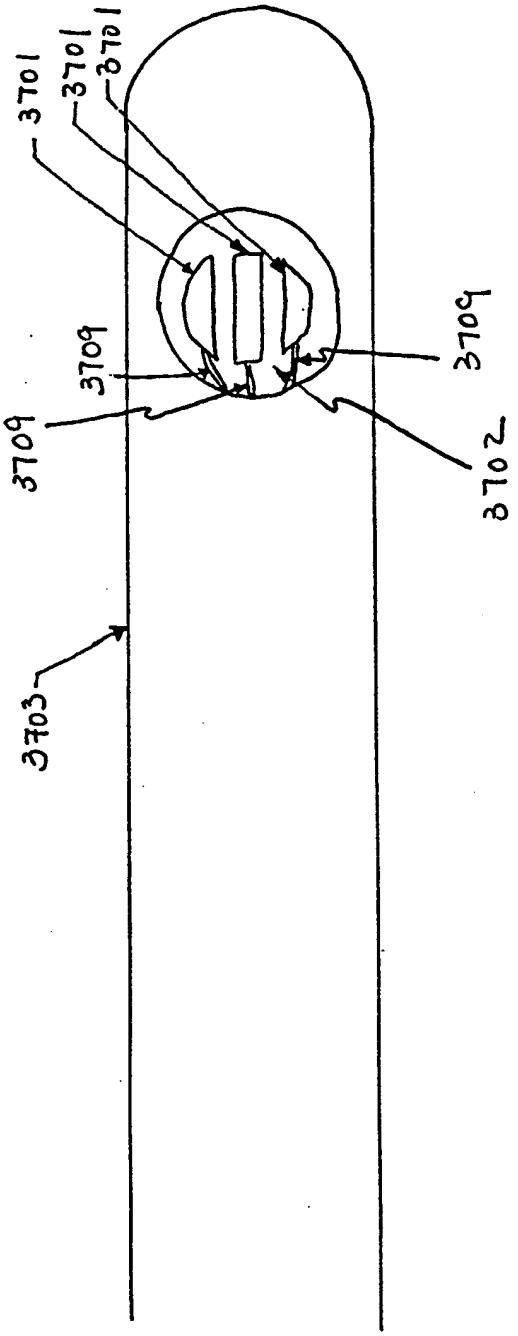

Figure 37D

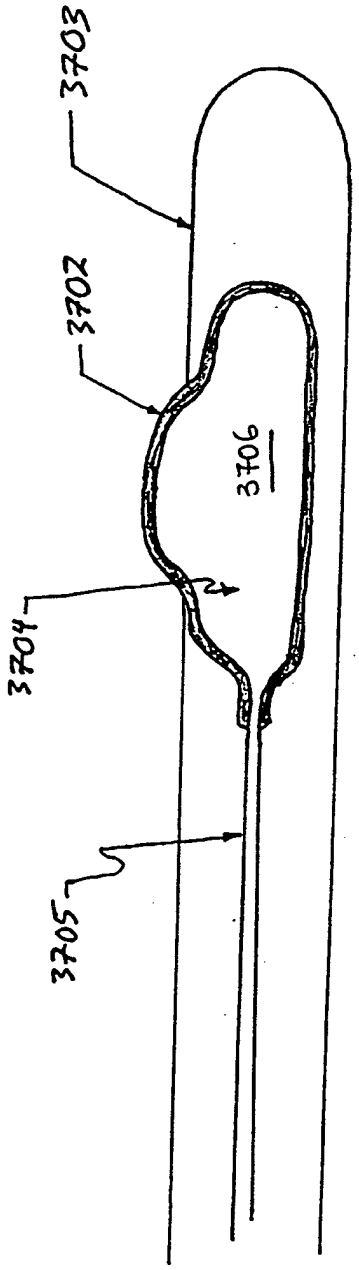

Figure 37E

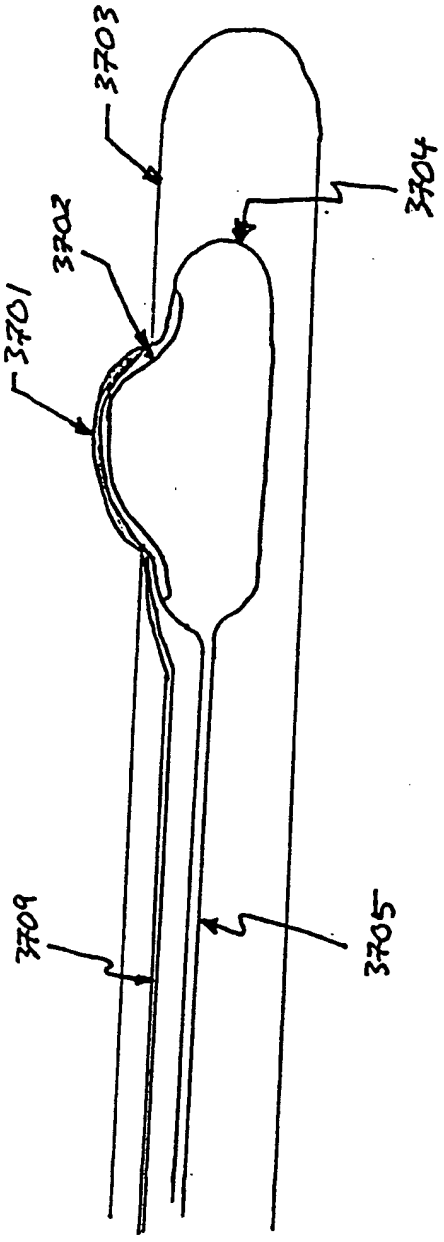

Figure 37F

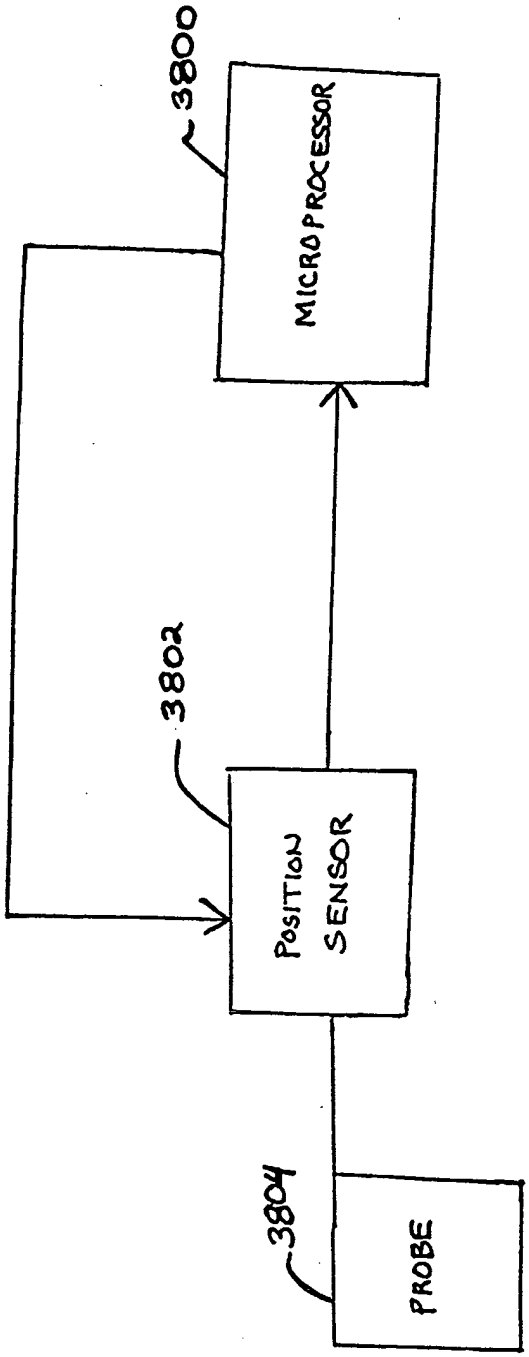

FIG 38

INTERNATIONAL SEARCH REPORT

Interna l Application No
PCT/US 99/18519

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B18/14

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 4 326 529 A (DOSS JAMES D ET AL) 27 April 1982 (1982-04-27) column 3, line 39 - line 57; figure 2 ---	1,14,15, 17
A	WO 95 31142 A (APPLIED MED RESOURCES) 23 November 1995 (1995-11-23) page 15, line 34 -page 16, line 14; figure 1 ---	1-3,10, 11,14, 15,17
A	US 5 749 871 A (MENDEZ G ANTONIO ET AL) 12 May 1998 (1998-05-12) column 6, line 39 - line 61; figures 2,3,5 column 8, line 4 - line 18; figure 7 --- -/--	1,15,17

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
30 November 1999	07/12/1999

Name and mailing address of the ISA	Authorized officer
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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 766 171 A (SILVESTRINI THOMAS A) 16 June 1998 (1998-06-16) column 7, line 58 -column 8, line 2; figure 3	1,17
A	EP 0 657 152 A (AMERICAN CYANAMID CO) 14 June 1995 (1995-06-14) column 8, line 48 - line 55; figure 3	1,17,18

INTERNATIONAL SEARCH REPORT

Inte .ional application No.
PCT/US 99/ 18519

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 20-28
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1 (iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/US 99/18519

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 4326529 A	27-04-1982	NONE	
WO 9531142 A	23-11-1995	US 5779698 A	14-07-1998
		EP 0760628 A	12-03-1997
		JP 10500333 T	13-01-1998
US 5749871 A	12-05-1998	AU 691198 B	14-05-1998
		AU 7601194 A	21-03-1995
		AU 8076998 A	08-10-1998
		BR 9407569 A	31-12-1996
		CA 2169943 A	02-03-1995
		EP 0715505 A	12-06-1996
		JP 9504447 T	06-05-1997
		NO 960716 A	22-04-1996
		PL 313222 A	10-06-1996
		WO 9505780 A	02-03-1995
		CN 1133001 A	09-10-1996
		US 5533999 A	09-07-1996
US 5766171 A	16-06-1998	AU 686743 B	12-02-1998
		AU 1700395 A	29-08-1995
		BR 9506762 A	07-10-1997
		CA 2183103 A	17-08-1995
		CN 1143900 A	26-02-1997
		EP 0743838 A	27-11-1996
		IL 112576 A	30-10-1998
		JP 9511161 T	11-11-1997
		SG 52621 A	28-09-1998
		WO 9521578 A	17-08-1995
EP 0657152 A	14-06-1995	US 5445636 A	29-08-1995
		US 5445637 A	29-08-1995
		AU 692799 B	18-06-1998
		AU 8023194 A	15-06-1995
		CA 2137211 A	07-06-1995
		JP 7250861 A	03-10-1995
		US 5885279 A	23-03-1999

CORRECTED VERSION*

PCT

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A1

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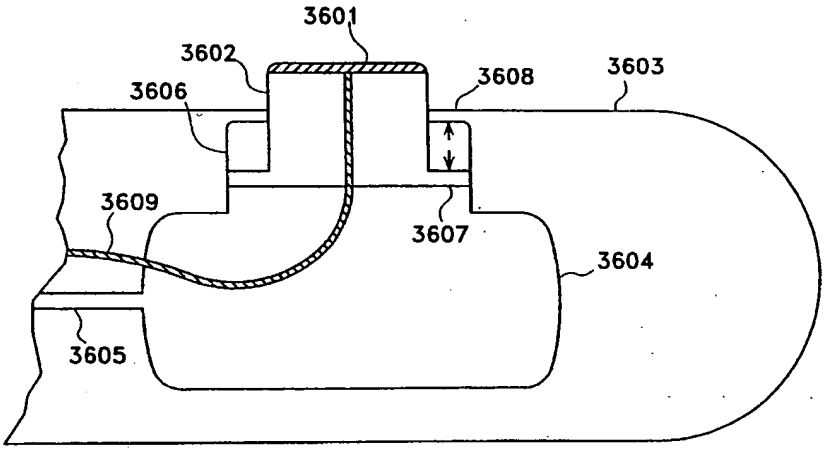
(72) Inventor; and
(75) Inventor/Applicant *(for US only)*: SILVESTRINI, Thomas, A. [US/US]; 1701 Las Trampas Road, Alamo, CA 94507 (US).

(74) Agents: CANNON, Alan, W. et al.; Morrison & Foerster LLP, 755 Page Mill Road, Palo Alto, CA 94304–1018 (US).

(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, EE, ES, FI, GB, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published
With international search report.

(54) Title: CORNEAL ELECTROSURGICAL PROBE WITH A VARIABLE-HEIGHT ACTIVE SITE



(57) Abstract

This invention is a device and procedure for the correction of optical abnormalities in a human eye. It involves use of an inventive electrosurgical energy probe with specific physical configurations. The process preferably utilizes a high frequency RF electrodesiccation or ablation device. The procedure involves the initial step of forming at least one access site allowing access to the corneal volume behind the Bowman's Layer. It preferably is placed in the anterior surface of the cornea through and ending posterior to the Bowman's layer of the eye. The electrosurgical probe is then introduced into the access site and, depending upon the visual abnormality to be corrected, the probe is activated to adjust the volume of the corneal stromal layers through ablation or desiccation. The shape of the volume desiccated or ablated is dependent upon the aberration to be corrected. The depth of tissue ablated may be adjusted by varying the height of the electrically active site of the electrosurgical probe. The height can be varied by raising or lowering a piston (3602) supporting the active site. The piston (3602) can be raised or lowered either pneumatically, or by attachment to an electrically controlled thermal expansion element which raises and lowers the piston as the thermal expansion element expands and contracts. Alternatively, the active site can be located on a balloon–type material which is pneumatically inflated to alter the height of the active sight above the nonconductive portion of the electrosurgical probe.

*(Referred to in PCT Gazette No. 31/2000, Section II)

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CORNEAL ELECTROSURGICAL PROBE WITH A VARIABLE-HEIGHT ACTIVE SITE

Field of the Invention

The field of invention relates to a procedure for the correction of optical abnormalities in a human eye. More specifically, the field of the invention relates to use of an electrosurgical energy probe which may be of a specific physical configuration as outlined below. This invention also includes suitable electrodes for performing the noted process. The process preferably utilizes a high frequency RF electro-desiccation or ablation device. The procedure involves the initial step of forming at least one access site allowing access to the corneal volume behind the Bowman's layer. It (the access site) preferably is placed in the anterior surface of the cornea through and ending posterior to the Bowman's layer of the eye. The electrosurgical probe is then introduced into the access site and, depending upon the visual abnormality to be corrected, the probe is activated to adjust the volume of the corneal stromal layers through ablation or desiccation. The shape of the volume desiccated or ablated is dependent upon the aberration to be corrected. For instance, if the optical aberration to be alleviated is hyperopia, a circular corneal volume reduction taking place about the outer periphery of the corneal mass may be accomplished. In other instances, such as for the treatment of astigmatism, certain smaller sections of the peripheral corneal volume may be shrunk. In certain circumstances, Bowman's layer may be cut to allow the curvature of the cornea to change after the corneal volume adjustment. These relief cuts may be radial, circular, semicircular or any other form appropriate for the optical adjustment needed.

Background of the Invention

Anomalies in the overall shape of the eye can cause visual disorders. Hyperopia ("farsightedness") occurs when the front-to-back distance in the eyeball is too short. In such a case, parallel rays originating greater than 20 feet from the eye focus behind the retina. In contrast, when the front-to-back distance of eyeball is too long, myopia ("nearsightedness") occurs and the focus of parallel rays entering the eye occurs in front of the retina. Astigmatism is a condition which occurs when the parallel rays of light do not focus to a single point within the eye, but rather have a variable focus due to the fact

that the cornea refracts light in a different meridian at different distances. Some degree of astigmatism is normal, but where it is pronounced, the astigmatism must be corrected.

Hyperopia, myopia, and astigmatism are usually corrected by glasses or contact lenses. Another method for correcting those disorders is through the implantation of polymeric rings (intrastromal corneal rings or "ICR's") in the eye's corneal stroma to change the curvature of the cornea. Previous work involving the implantation of polymethylmethacrylate (PMMA) rings, allograft corneal tissue, and hydrogels is well documented. One of the ring devices involves a split ring design which is inserted into a channel previously dissected in the stromal layer of the cornea. A minimally invasive incision is used both for producing the channel and for inserting the implant. See, for instance, the use of PMMA intrastromal rings in U.S. Patent Nos. 4,452,235 to Reynolds; 4,671,276 to Reynolds; 4,766,895 to Reynolds; and 4,961,744 to Kilmer et al. Surgical methods for the correction of such disorders are known. Such methods include radial keratotomy (see, e.g., U.S. Patent Nos. 4,815,463 and 4,688,570) and laser corneal ablation (see, e.g., U.S. Patent No. 4,941,093).

There are other procedures for reshaping the surface of the cornea. Some involve surgery; others do not. Two patents dealing with the nonsurgical reshaping of the cornea are U.S. Patent Nos. 4,326,529 to Doss, et al. and 4,381,007 to Doss. Both of these patents deal with the use of radio frequency energy to reshape the cornea of an eye. These involve the use of RF probes which are introduced non-invasively onto the cornea. They each involve an RF generating source which is placed on the anterior surface of the cornea and utilize saline solution to cool the corneal surface as the radio frequency current enters the eye. The RF apparently heats various stroma within the cornea and thereby reshapes the cornea as a biological response to the heat produced by the RF.

Other invasive ophthalmic surgical devices include U.S. Patent No. 4,805,616, to Pao, which describes a bipolar probe device used in ophthalmic surgery. The device is only described in the performance of anterior capsulotomies. In that procedure, a limbal incision is made and the active probe tip is inserted between the anterior capsule of the eye's lens and the corneal endothelium. The anterior capsule is sequentially coagulated, becomes extremely friable, and then is removed by mechanical

penetration with an additional mechanical device. No mention of treatment of a cornea is found.

Similarly, two patents to Easley et al., U.S. Patent Nos. 5,201,730 and 5,203,353, show devices for penetrating and working in the vitreous humor of an eye using combination stripping tools and aspirators. The disclosed instrument may also have a bipolar diathermy device with an exterior needle surrounding and coaxial to a fiberoptic member. The diathermy device is used only to coagulate bleeding vessels found on the retinal surface or beneath preretinal membranes. No mention of treating the cornea is mentioned.

Two related applications, U.S. Patent No. 5,025,811 to Dobrogowski et al., and 5,174,304, to Latina et al., show noninvasive methods for focal transcleral destruction of living human eye tissue. In general, these devices and their underlying procedures involve the use of electric currents for ablating eye tissue, particularly the ciliary process. Again, no mention of cornea treatment is seen.

This invention involves the introduction of an electrosurgical probe into the layers of the cornea to modify local sections of that corneal mass.

There are a variety of electrosurgical devices known. For instance, Hetzel, U.S. Patent No. 4,033,351, shows a bipolar cutting electrode for high frequency surgery. The electrode shows what is said to be an improved electrode design having a number of metal tips.

U.S. Patent No. 4,202,337, to Hren et al., shows a similar electrosurgical device for cutting or coagulation. It has a nonconductive handle with a blade assembly having a number of electrodes and an insulation member separating the various electrodes.

A similar and related patent to Degler Jr. et al., U.S. Patent No. 4,228,800, shows an electrosurgical knife in which the blade assembly has a center electrode of specified thickness, insulation members secured to the center electrode, and a number of side electrodes secured to the insulation members. None of these devices discuss practice of a surgical procedure upon the posterior regions of a cornea.

U.S. Patent No. 4,799,478, to Fedorov et al. teaches a device for the coagulation of biological tissues, preferably corneal tissue. The device disclosed by Fedorov et al. appears to be merely a heating device with a manner of carefully controlling

the depth to which the heater or coagulator is introduced. The device is said to be useful for coagulation of biological tissue and the concept of changing "the curvature" of "eye tissues, e.g., cornea" is noted. The patent mentions the need for high accuracy to reach the goal of "to carry out coagulation of the eye cornea to a specific depth." Although it is not clear what result Fedorov et al. wishes to obtain in this first patent, Fedorov et al. in U.S. Patent No. 4,907,587, mentions the use of thermal coagulation of the cornea along certain corneal surfaces to correct various optical aberrations in the eye. It should be noted that neither of these patents suggests the use of ablation or desiccation from the reverse side of the Bowman's layer to effect any change in the anterior corneal surface.

Summary of the Invention

An aspect of the invention provides a method of altering the shape of the cornea, often, the anterior surface curvature of the cornea. The invention also includes certain electrosurgical probe configurations useful in this process. The procedure, in its preferred variations, does not entail significant surgical modification of the anterior corneal surface or of the Bowman's layer of the eye, except, in certain situations, adding surface incisions to act either as a stress relief function or to provide access for the electrosurgical probe.

An electrosurgical probe is a significant aspect of this invention. It is used, preferably in desiccation or ablation mode, to change the volume of the mass of the cornea posterior to the Bowman's layer and found in the stromal regions of the cornea. By selectively modifying the volume of these regions, small amounts of the cornea may be controllably removed or shrunk and, upon removal of the electrosurgical probe from the cornea, the curvature of the anterior surface of the cornea will have changed and the refractive path of light entering the eye will be changed. As noted above, surface incisions may later be added to permit the anterior of the cornea, in particular, Bowman's layer, to conform to the underlying corneal tissue removal (volume change), thereby allowing for change in anterior corneal curvature.

The inventive procedure may be used for the treatment of hyperopia (farsightedness) or myopia. In this procedure, a small incision or access site may be made in the anterior surface of the cornea, which incision extends down through the Bowman's

layer or through the sclera and into the intrastromal volume of the cornea. An electrosurgical probe may be introduced through the incision and guided around within the corneal stroma from the outer periphery of the cornea. Activation of the electrosurgical probe in an ablation mode will cause vaporization of the regions of the cornea adjacent to the active areas of the probe. Activating the probe in a desiccation mode will shrink or necrose the region of the cornea adjacent to the active areas of the probe. After an appropriate necrosis, removal or shrinking of material is accomplished, the probe is removed and the anterior surface then relaxes to conform to the collapse or shrinkage of tissue formed by electrosurgical treatment of the corneal stromal tissue. In some instances, a modest incision in the anterior of the cornea may be desirable to allow curvature relaxation of the corneal anterior surface.

Another preferred procedure includes the alleviation of astigmatism by similar procedure. Small partial depth incisions may be made into the anterior surface of the cornea through Bowman's layer or through the sclera adjacent to the cornea to get under Bowman's layer, but not reaching so far as the posterior corneal surface or the anterior chamber. In a general sense, these initial incisions are made in the regions of the cornea or sclera to allow the electrosurgical probe to reach the corneal mass below the anterior surface which must be reduced to produce a symmetric corneal surface. In any event, an electrosurgical probe is then introduced through the incisions and a selected amount of material is removed or desiccated to alleviate the nonregularity of the corneal anterior surface.

Also as a part of this invention are certain monopolar, bipolar, and sesquipolar electrosurgical probe designs which are especially suitable for producing the specific tissue removal patterns desired in this procedure.

Also as part of this invention are certain variable-height active site electrosurgical probe designs. In one embodiment the active site of the electrosurgical probe is affixed to the top of a piston which can be raised and lowered within the nonconductive material of the electrosurgical probe. In this manner the height of the active site above the nonconductive portion of the probe can be varied, thereby allowing the surgeon to vary the depth of tissue removed during a procedure. Several possible means of raising and lowering the piston within the nonconductive probe are disclosed including

pneumatically raising and lowering the piston. Another possible means of raising and lowering the piston includes the use of a thermal expansion element which raises and lowers the piston as the thermal expansion element expands and contracts.

In another embodiment of the present invention a pneumatic balloon-type variable height electrosurgical probe is utilized where the active site region is raised and lowered in relation to the nonconductive portion of the electrosurgical probe by pneumatically inflating the balloon to which the active site is attached. In this manner the height of the active site above the nonconductive portion of the probe can be varied, thereby allowing the surgeon to vary the depth of tissue removed during a procedure. In the pneumatic balloon-type variable height electrosurgical probe the active site region can be formed from one or several strips of conductive material affixed to the balloon material by an adhesive in such a configuration to allow the balloon material to expand and contract during the raising and lowering of the active site region. In another embodiment, the active site region is formed by depositing a thin film of conductive material on the balloon material in such a manner to allow the balloon to expand and contract.

Brief Description of the Drawings

Figure 1 is a schematic illustration of a horizontal section of the eye.

Figure 2 is a schematic illustration of the anterior portion of the eye, showing various layers of the cornea.

Figures 3A to **3E** show a schematic process for treatment of hyperopia using the procedure of this invention.

Figures 4A to **4D** show schematic diagrams of astigmatic and normal eyes.

Figures 5-11 A and **B** show top and side views of inventive circular RF electrosurgical probes.

Figures 5-9 C and **D** show side views of alternative embodiments of inventive circular RF electrosurgical probes.

Figures 12-19 A and **B** show top and side views of inventive straight RF electrosurgical probes.

Figures 12-14 C and **D** show side views of alternative embodiments of inventive straight RF electrosurgical probes.

Figures 17C and **D** are top views of alternative embodiments of straight RF electrosurgical probes.

Figures 20 A and **B**, and **21 A, B** and **C** show top (A and C) and side (B) views of inventive disc and washer RF electrosurgical probes.

Figures 20C and **20D** are side sectional views of alternative embodiments of the probe of **Figure 20A**.

Figures 21D and **21E** are side sectional views of alternative embodiments of the probe of **Figure 21A**.

Figures 21F and **21G** are side sectional views of alternative embodiments of the probe of **Figure 21C**.

Figures 22A and **B** illustrate sesquipolar probe configurations.

Figures 23A-G are schematic diagrams showing top views of eyes wherein various processes for electrosurgically altering corneal curvature have been carried out.

Figures 24A-F illustrate an apparatus for positioning a circular electrosurgical probe to perform corneal tissue removal according to the present invention.

Figures 25-34 A and **B** show top views of inventive circular RF electrosurgical probes with inwardly-directed contact end portions and side views of the inwardly-directed contact end portions.

Figures 25-28 C and **D** show side views of alternative embodiments of inwardly-directed contact end portions of inventive circular RF electrosurgical probes with inwardly-directed contact end portions.

Figure 35 shows a complementary pair of inventive circular RF electrosurgical probes with inwardly-directed contact end portions.

Figure 36A is a side view of an electrosurgical probe having a variable-height active site controlled by a pneumatically activated piston.

Figures 36B & C are cross-sectional side views of an electrosurgical probe having a variable-height active site controlled by a pneumatically activated piston as shown in **Figure 36A**.

Figure 36 D is a cross-sectional side view of a piston-type variable-height probe as in **Figures 36A-C** with a return spring for lowering the piston.

Figure 36E is a side view of an electrosurgical probe with a rounded active site region.

Figure 36F is a cross-sectional side view of an electrosurgical probe with a piston adapted to accept different active site regions of differing size and shape.

Figure 36G is a cross-sectional side view of a piston-type variable-height active site electrosurgical probe which is adjusted by a thermal expansion element.

Figure 37A is a side view of an electrosurgical probe having a variable-height active site controlled by a pneumatically activated balloon.

Figure 37B is a top view of a pneumatic balloon type variable-height active site electrosurgical probe.

Figure 37C is a cross-sectional side view of a pneumatic balloon-type variable-height active site electrosurgical probe.

Figure 37D is a top view of a pneumatic balloon-type variable-height active site electrosurgical probe having an active site formed from multiple conductive strips.

Figure 37E is a cross-sectional side view of a pneumatic balloon-type variable-height active site electrosurgical probe utilizing a full balloon within a pressure chamber.

Figure 37F is a cross-sectional side view of a pneumatic balloon-type variable-height active site electrosurgical probe utilizing an active site that is sputter-deposited onto the surface of a balloon.

Figure 38 shows a microprocessor control loop for the probe in accordance with an aspect of the invention.

Detailed Description of the Invention

Prior to explaining the details of the inventive procedures and devices, a short explanation of the physiology of the eye is needed.

Figure 1 shows a horizontal cross-section of the eye with the globe (11) of the eye resembling a sphere with an anterior bulged spherical portion representing the cornea (12).

The globe (11) of the eye consists of three concentric coverings enclosing the various transparent media through which the light must pass before reaching the light-

sensitive retina (18). The outermost covering is a fibrous protective portion the posterior five-sixths of which is white and opaque and called the sclera (13), and sometimes referred to as the white of the eye where visible to the front. The anterior one-sixth of this outer layer is the transparent cornea (12).

A middle covering is mainly vascular and nutritive in function and is made up of the choroid, ciliary body (16), and iris (17). The choroid generally functions to maintain the retina (18). The ciliary body (16) is involved in suspending the lens (21) and accommodation of the lens. The iris (17) is the most anterior portion of the middle covering of the eye and is arranged in a frontal plane. It is a thin circular disc similar in function to the diaphragm of a camera, and is perforated near its center by a circular aperture called the pupil (19). The size of the pupil varies to regulate the amount of light which reaches the retina (18). It contracts also to accommodation, which serves to sharpen the focus by diminishing spherical aberration. The iris divides the space between the cornea (12) and the lens (21) into an anterior chamber (22) and the posterior chamber (23). The innermost portion of covering is the retina (18), consisting of nerve elements which form the true receptive portion for visual impressions.

The retina (18) is a part of the brain arising as an outgrowth from the fore-brain, with the optic nerve (24) serving as a fiber tract connecting the retina part of the brain with the fore-brain. A layer of rods and cones, lying just beneath a pigmented epithelium on the anterior wall of the retina serve as visual cells or photoreceptors which transform physical energy (light) into nerve impulses. The vitreous body (26) is a transparent gelatinous mass which fills the posterior four-fifths of the globe (11). At its sides it supports the ciliary body (16) and the retina (18). A frontal saucer-shaped depression houses the lens.

The lens (21) of the eye is a transparent bi-convex body of crystalline appearance placed between the iris (17) and vitreous body (26). Its axial diameter varies markedly with accommodation. A ciliary zonule (27), consisting of transparent fibers passing between the ciliary body (16) and lens (21) serves to hold the lens (21) in position and enables the ciliary muscle to act on it.

Referring again to the cornea (12), this outermost fibrous transparent coating resembles a watch glass. Its curvature is somewhat greater than the rest of the globe and is

ideally spherical in nature. However, often it is more curved in one meridian than another giving rise to astigmatism. Most of the refraction of the eye takes place through the cornea.

Figure 2 is a more detailed drawing of the anterior portion of the globe showing the various layers of the cornea (12) making up the epithelium (31).

An anterior limiting lamella (33), referred to as Bowman's membrane or layer, is positioned between the epithelium (31) and the stroma (32) of the cornea. The various stroma (32) between the Bowman's layer (33) and the Descemet's membrane (34) are referred to as the corneal mass. The corneal stroma (32) are made up of lamellae having bands of fibrils parallel to each other and crossing the whole of the cornea. While most of the fibrous bands are parallel to the surface, some are oblique, especially anteriorly. A posterior limiting lamella (34) is referred to as Descemet's membrane. It is a strong membrane sharply defined from the stroma (32) and resistant to pathological processes of the cornea.

The endothelium (36) is the most posterior layer of the cornea and consists of a single layer of cells and function to maintain transparency of the cornea (12). These epithelial cells are rich in glycogen, enzymes and acetylcholine and their activity regulates the transport of water and electrolytes through the lamellae of the cornea (12). The limbus (37) is the transition zone between the conjunctiva (38) and sclera on the one hand and the cornea (12) on the other.

There are a variety of different electrical surgical delivery probes which would be suitable in this invention. In general, there are two distinct electrosurgical delivery probe types: the monopolar probe and the bipolar probe. An in-between electrosurgical configuration applicable to this invention also exists and is known as sesquipolar. In each instance, some section of the human body is used to complete a circuit between one pole and the other. In the monopolar probe device, there is a single active contact which is inserted or otherwise contacted with the human body and it is the site at which some body activity, e.g., desiccation, ablation, necrosis, fulguration, or the like, takes place. To complete the circuit in a monopolar device, there must be another contact which is inactive and placed against the body in a location from the active contact. By "inactive" is meant that only an insignificant temperature rise occurs at that contact point. One such

method of insuring that the inactive electrode is in fact "inactive" is to make it quite large in area. This causes the current to spread over a large area for completion of the circuit.

A bipolar electrode typically has two equal area active electrodes contained in the same electrode probe-handle structure. This symmetric bipolar electrode design produces a significant temperature rise at both electrodes.

In a monopolar or sesquipolar configuration, only one electrode has an area of tissue contact producing significant temperature rise. Unlike the monopolar configuration, however, the sesquipolar return electrode is not so remote, and thereby limits current flow through the body to the nearby return electrode. The return electrode area in the sesquipolar configuration electrode is usually at least three times the area of the active electrode and produces little or no tissue effect. In some designs, the sesquipolar return electrode may be found on the electrode probe-handle structure while on other designs it may be separately located in a non-remote region of the body.

There are a variety of effects that may occur depending upon the electrosurgical mode desired. For instance, there are both high temperature and low temperature desiccation effects when the active electrosurgical probe contact(s) are used to promote tissue desiccation. The resistance of the tissue in contact with the active probe electrode obviously varies with the tissue temperature and water content of the tissue. A low temperature desiccation effect involves heating such that the temperature-time product causes tissue necrosis with little immediate denaturation or discoloration of the tissue. A high temperature desiccation includes heating tissue near the conducting probe contact to approach or slightly exceed 100° C. In the low temperature variation of this procedure, there is a transient decrease in local tissue impedance with little drying of tissue. But in the high temperature variation, there are significant increases in local tissue impedance and also significant in local tissue desiccation.

In the ablation mode, the electrosurgical energy density delivered largely causes the tissue near the probe contact to vaporize. The temperature at the electrode/tissue interface is increased significantly past the point of steam formation. The effect of electrical resistance varies during a specific radio frequency (RF) cycle and although there is sparking, carbonization is not usually significant and the effects of the device are relatively rapid.

Electrosurgical ablation and cutting produce an effect where a thin layer of tissue is vaporized (cutting) or where a larger section of tissue is vaporized (ablation). The line between "cutting" and "ablation" is not always clear.

Blended mode is essentially a combination of the cutting and coagulation (desiccation) modes. In blended mode, cutting or ablation with hemostasis is achieved.

In the procedure specified below as the invention, the electrosurgical probes may be operated in cutting, ablation, desiccation or blended modes. Herein, the term "volume change" or "volume modification" refers to the corneal mass being either necrosed, desiccated, ablated or subject to some combination thereof.

It is quite rare that the current flow through the device is DC. The current is typically a very high frequency alternating current, typically on the order of 500KHz or more. Additionally, the RF energy is often delivered in a pulsed or in a more continuous, non-pulsed operation depending on the exact effects desired. Some residual heating will take place no matter which course is taken. For further information concerning the electrical characteristics of electrosurgical waveforms, and electrosurgery in general, please refer to J.A. Pearce, Electrosurgery, John Wiley & Sons, 1986; U.S. Patent No. 4,438,766 to Bowers; the SSE2K Electrosurgical Generator Service and Instruction Manuals (1982, 1980), the SSE2L Electrosurgical Generator Instruction Manual (1991), and the Force 2 Electrosurgical Generator Instruction Manual (1993), Valleylab. These references are incorporated by reference herein in their entireties.

With this lengthy background in place, please refer to **Figures 3A** through **3D**. This series of figures shows, in schematic fashion, one procedure for treating hyperopia (farsightedness), myopia, or astigmatism. This schematic procedure shows features which may be common to all of the processes of this invention. Generically, the procedure includes the step of producing one or more incisions, often towards the periphery of the cornea. These incisions penetrate Bowman's layer in the anterior surface of the cornea and extend down into, as defined above, "the corneal mass" or "corneal volume." It is also contemplated that the electrosurgical probe may be inserted into the corneal volume without penetration of the anterior surface of the cornea, e.g., by access through a partial depth incision made in the sclera next to the cornea.

In any event, if an anterior access partial depth incision is contemplated, an optional step at this point may be the insertion of a non-electrosurgical lamellar separator to separate the various stroma lamellae within the cornea at the depth of the entry incision. This allows the subsequent step of inserting the electrosurgical probe to take place with greater ease. The probe itself may serve the function of intralamellar separator, if so desired.

The electrosurgical probe is introduced into the stromal lamellar cavity so produced. Depending upon the design of the inserted electrosurgical probe and on the refractive effect desired, the probe is moved inside the intralamellar space previously formed and activated to desiccate or ablate specific geometric regions of the cornea.

The probe may be energized by a common electrosurgical generator such as the Force 2 manufactured by Valleylab, Inc. The generator includes settings for providing the appropriate electrosurgical waveforms for cutting, coagulation or blended modes. The wave shape for each mode is specified in the Valleylab generator manual. Cutting is performed with a 510KHz continuous sinusoid. Coagulation (desiccation) employs a 510KHz damped sinusoidal burst with a repetition frequency of 31KHz. In blended modes, the generator outputs a 510KHz sinusoidal burst at various duty cycles recurring at 31KHz. Those skilled in the art will recognize that the present invention is not limited to the generators or particular wave shapes and corresponding electrical characteristics disclosed herein.

The probe initially may be energized at a low power setting (*e.g.*, 5 watts or lower) for approximately 1-5 seconds or longer. During activation of the probe, the surgeon observes the volume reduction process to ensure that tissue is being safely removed or shrunk from the proper corneal regions. Typically, this observation may be performed in real time through an ophthalmic microscope.

Desirably, after the completion of the corneal volume reduction step, the curvature of the corneal surface is then measured. Curvature is typically measured after the probe has been removed to avoid distortion of the corneal surface by the probe itself. One common method for measuring corneal curvature employs the Placido ring technique embodied in the Corneal Topography System manufactured by Eyesys of Houston, Texas. Curvature may also be measured using the technique described in allowed U.S. Patent

Application Ser. No. 08/200,241, assigned to the assignee of the present invention, and incorporated by reference herein. The procedure may be repeated if insufficient correction has occurred. When repeating the procedure, the surgeon may increase the output power to reduce a greater volume of tissue until the desired effect is achieved. If needed, Bowman's layer and a small amount of underlying stromal tissue may be lightly cut on the anterior surface adjacent to or above the site of the volume reduction to allow the anterior corneal surface to change.

Returning to the specifics of **Figures 3A** to **3D**, **Figure 3A** shows an eye (100) having a pupil (102) and a cornea (104). In the outer radius of cornea (104) are two small partial depth incisions (106) which have been cut through Bowman's layer into the corneal mass as shown in **Figures 1** and **2**. These incisions may be cut radially or circumferentially and are shown for discussion purposes to be radial.

It should be understood, however, that although two access partial depth incisions (106) have been portrayed in **Figure 3A**, the number of such access sites (106) is not important. If a semi-circular lamellar separator (108) as shown in **Figure 3B** is used, then the number of access sites (106) may be desirably two in number. If lamellar separators of shorter arc segments are used, more numerous slits may be desired. If a nearly circular lamellar separator or electrosurgical probe is used, a single access site (106) may be sufficient.

Figure 3B shows the introduction of the optional dissector blade or lamellar separator (108) to separate the lamella found in the cornea. Alternatively, the probe itself may be used to separate the lamella. The separator (108) is rotated until a circular channel is made in the corneal periphery, and is rotated back out of the eye. A similar procedure takes place on the other access site as shown in **Figures 3A** and **3B**. **Figure 3C** shows the insertion of an electrosurgical probe (110) into the route formed in the intrastromal region shown in **Figure 3B**. The probe may be energized following complete insertion or may be energized in a stop, move and activate mode. The step of removing and/or shrinking tissue is continued until sufficient tissue has been ablated or desiccated to achieve the desired refractive effects.

Figure 3D shows the eye (100) after completion of the ablation procedure. It may be desirable to place a small stitch (112) or biocompatible glues developed for

wound closure, such as fibrinogen, cyanoacrylate, etc. in any access site (106) in the cornea to ensure healing of the access site and minimize the potential for infection. **Figure 3E** shows the eye (100) following relief cuts (114) that may be necessary in some instances to allow the anterior corneal surface to more closely conform to the underlying corneal tissue removal (volume change) thereby allowing for greater change in anterior corneal curvature. These relief cuts may be circumferential as shown or they may be radial depending on the desired refractive effect. Further, the relief cuts may be continuous or may be interrupted as shown. In any case, these cuts may penetrate Bowman's layer and possibly a portion of the underlying corneal stroma.

The above-description generally indicates the method of the present invention. Specific probe configurations and method of treatment will be described in the examples below.

It should be apparent from the description above, that the step of desiccating, necrosing or ablating the tissue from within the corneal mass lessens the volume of that mass in specific regions of the cornea. Consequently, the anterior sections of the cornea will become flatter or steeper and will alleviate the improper previous refraction of light. Some of the possible changes in corneal thickness and their relationship to the radius of curvature of the central corneal surface are described in Jose Barraquer: Father of Modern Refractive Keratoplasty, in Refractive and Corneal Surgery, Vol. 5, May/June 1989, pages 177-193, which is hereby incorporated by reference in its entirety. This paper describes the so-called "Law of Thickness" which indicates that when corneal volume is reduced in the periphery, central corneal steepening occurs and when a volume of tissue is removed in the center, central corneal flattening occurs. The inventive electrosurgical method and devices aim to reduce corneal volume in controlled geometric areas of the corneal stroma to achieve refractive correction.

The method and devices of the present invention may also be useful in the treatment of astigmatism. Astigmatism occurs, generally, when the curvature of the anterior surface of the cornea is not regular as one passes about the meridians on the anterior surface of the cornea resulting in a steep and flat axis (the astigmatic axis). **Figure 4A** and **4B** are schematic perspective views that show an astigmatic and normal eye, respectively. In an astigmatic eye, two axes are generally identified, corresponding to the

steepest (120) and flattest (122) axis of curvature. The steepest axis is also known as the axis of astigmatism (120). To correct astigmatism using this invention, one must flatten the curvature of the astigmatic axis such that the cornea becomes reasonably symmetrical and more spherical. **Figure 4B** shows a normal eye, that is, one in which the curvature of all axes are the same. **Figures 4C** and **4D** show schematic topographical curvature maps of an astigmatic and of a non-astigmatic eye, respectively. In **Figure 4C**, region 130 is the steep region whereas region 132 is flatter.

Other configurations of access sites and controlled removal of corneal tissue are apparent. These will be discussed for particular applications in the examples below. Further, it should be apparent to one appreciating the design of such electrosurgical RF probes, that the shape need not be nearly circular. It may be, much in the same way as were the lamellar separators (108) in **Figure 3B**, that the probes have lesser arc length or are straight for alleviating hyperopia. In fact, for treating hyperopia or other maladies, the probe may be of any convenient shape designed to ablate the tissue at hand. Such shapes will be discussed in more detail below. Further it may be noted that the handles of the probes may be straight or bent. The handle also may be a circular barrel to facilitate the vision of the surgeon. A bent handle may allow greater facility of use within the small confines found behind an access site as shown in the above drawings. Additionally, the procedures and devices of the present invention may be useful in the treatment of more than one indication; for example myopia and astigmatism or hyperopia and astigmatism.

Figures 5-11 A and **B** show top (A) and side (B) views of circular electrosurgical probes suitable for use in the schematic procedure described above. The terms "circular probe" and "substantially hook-shaped probe" refer to an arcuate or substantially circular probe or a probe that otherwise subtends any radial angle of a substantially circular geometric figure. Note that these circular probes may form part of a complementary set, as described below with respect to the circular probes of **Figures 25**, et seq.

Figures 5A and **B** show a circular RF electrosurgical probe with two active sites that operate in monopolar or sesquipolar modes. The probe (200) includes a shaft (202) and two active sites (204), each active site having an arc of less than about 180°, preferably less than about 90°. The probe has an inner diameter of approximately 6.5 mm

and an outer diameter of approximately 8.5 mm. The single source of RF energy (206) is fed in through the insulator (208) making up the probe (200). **Figures 6A** and **B** show a circular RF electrosurgical probe (210) with a single active site (212) at the tip. Again, the single source of RF energy (214) is fed in through the insulator making up the probe. **Figure 7A** and **7B** show a circular RF electrosurgical probe (220) with a single active site (222) extending the length of the circular portion of the probe. Once more, the single source of RF energy (224) is fed in through the insulator (226) making up the probe. **Figures 8A** and **B** show a circular RF electrosurgical probe (230) with two active sites (232) near the tip of the probe that operate in bipolar fashion. Two sources of RF energy (234 and 236) are fed in through the insulator (238) making up the probe. **Figures 9A** and **B** show a circular RF electrosurgical probe (240) with a single active site (242) near the tip, the active site shown in **Figure 9A** to be on the top part of the probe. A single source of RF energy (244) is fed in through the insulator (246). **Figures 10A** and **B** and **11A** and **11B** show other circular RF electrosurgical probes (250 and 260 respectively) with single active sites (252 and 262 respectively) near the tips of the probes. A single source of RF energy (254 and 264) is fed in through each probe. **Figure 10B** shows the active site (252) to be located at the tip but exposed on one side and **Figure 11B** shows the active site (262) to be located at the tip but insulated on the top and thus exposed on one side only. Both probes depicted in **Figures 10 A** and **B** and **11 A** and **B** are designed to contact tissue in either the forward or retracting direction to the active site on the probe, the retracting direction.

Figures 5-9 C and **D** show side views of circular electrosurgical probes in which the active sites applied to tissue are raised above a substantial portion of the nonconductive area of the probe. The height of the raised active site controls the depth of the tissue removed. This height is approximately in the range of 0.0-0.55 mm. The raised active site pushes tissue in contact therewith above the larger nonconductive area of the probe. The unraised nonconductive portion acts as a backstop or footplate with respect to the raised active site. In the absence of a raised active site, uniform pressure must be maintained against the tissue in order to remove tissue of uniform depth. With the raised active site of the present invention, uniform depth is easier to achieve without fine control of the applied pressure because the footplate (larger nonconductive area) acts as a stop to

prevent the active site from advancing into the tissue to a depth deeper than the height of the raised active site. The active site also may be lower than contact end. That is, the active site may be varied within a well or sunken area.

A set of probes having active sites raised to different heights may be provided, so that the surgeon may select the proper probe depending upon the depth (and therefore volume) of tissue to be removed. During performance of a procedure, the surgeon may use multiple probes, e.g., increasing in active site height, until the desired depth of tissue removal is achieved. Alternatively, a single probe may be adapted for use with removable active sites of different heights. The active sites may be coupled to the rest of the probe by any number of well known removable means, including but not limited to pressfit, snap engagement screws, or slideable mounts.

A probe having a variable height active site may be provided, allowing the surgeon to adjust the height of the active site depending on the depth (and therefore the volume) of tissue to be removed. During performance of a procedure, the surgeon may vary the height of the active site until the desired depth of tissue removal is achieved.

More particularly, the height of the active site of a probe can be varied by several possible mechanisms. **Figures 36A-36G** show one particular embodiment where an active site (3601) is a conductive region located on the top of a piston (3602). Raising and lowering the piston within an insulator making up a probe (3603) varies the height of the active site allowing the surgeon to control the depth of tissue material removed.

The piston (3602) in the embodiments shown in **Figure 36A-36G** can be raised and lowered by several alternative means. In one embodiment, shown in **Figure 36B**, the piston (3602) is raised and lowered pneumatically within a hole (3606). The piston (3602) forms an airtight seal on a pressure chamber (3604) located within the probe, which is connected to an air pressure line (3605). Several possible means of forming an airtight seal can be employed including, but not limited to, use of O-ring seals, or other covenient or suitable means for providing an airtight seal between the piston and the probe such as a flexible polymer coating on the perimeter of the piston. The hole (3606) is formed in the wall of the pressure chamber (3604) and extends through the nonconducting probe (3603) to the exterior of the probe. The piston (3602) moves within the hole (3606) to vary the height of the active site (3601) above the surface of the nonconductive probe

(3603). As pressure within the pressure chamber (3604) increases, the piston (3602) is forced in an upward direction, thereby increasing the height of the active site (3601) above the nonconductive portion of the probe (3603). Conversely, reducing air pressure within the chamber causes the piston to move in a downward direction , thereby reducing the height of the active site (3601) above the nonconductive portion of the probe (3603). In this manner the pressure chamber (3604) and air act as an actuator to raise and lower the piston (3602). As shown in **Figure 36C**, a flange portion (3608) of the probe (3603) comes in contact with a piston flange (3607) to prevent the piston (3602) from "popping out" of the probe (3603) when excessive air pressure is applied by the surgeon. The air pressure line (3605) passes through the nonconductive material making up the probe (3603) to the probe handle. The line (3605) is attached to and is connected to a pressure regulator (not shown), which can be controlled by the surgeon to change the pressure within the pressure chamber (3604), thereby adjusting the height of the active site (3601). While the present invention utilizes air, other gases or even liquids can be used to increase or decrease pressure within the pressure chamber (3604), thereby raising or lowering the piston (3602), respectively. It is important that there be an airtight seal between the piston (3602) and the nonconductive portion of the probe (3603) to prevent air, or other gasses within the pressure chamber, from leaking into the corneal tissue during the procedure. An RF energy line (3609) passes through the nonconductive material of the probe (3603) and through the piston (3602) to connect to the active site (3601).

An alternate embodiment of the piston-type variable-height electrosurgical probe is shown in **Figure 36D**, a cross-sectional side view, wherein a return spring (3610) is used to bias or to provide a force to lower the piston (3602) when the pressure within the pressure chamber (3604) decreases. The spring (3610) biases the piston (3602) in a direction of decreasing the height of the active site (3601) i.e. in a downward direction. The piston (3602) has a lower flange (3607) which forms an substantially airtight seal against the side of the nonconductive portion of the probe (3603), thus preventing pressurized air within the pressure chamber (3604) from escaping at an appreciable rate. The spring (3610) is coiled around the piston (3602) and pushes at one end against the piston flange (3607) and at the other end against a probe flange (3608). As pressure within the pressure chamber (3604) decreases, the force of the spring pushing on the piston flange

(3607) causes the piston (3602) to move in a downward direction, thereby decreasing the height of the active site (3601) above the nonconductive portion of the probe (3603). Both the pressure chamber (3604) and the spring (3610) act as an actuator to raise and lower the piston (3602).

The active site (3601) of the piston-type variable-height probe shown in **Figures 36A-36G** is formed from a conductive layer, made from a material such as copper or stainless steel and having a thickness in a range of 10 microns to about 150 microns or thicker, which is attached to the upper surface of the piston (3602) by a heat resistant adhesive or other heat resistant fasteners. A heat resistant adhesive is used to prevent the active site (3601) from becoming dislodged during the repeated heating and cooling cycles of the ablation procedure. While the active site (3601) shown in **Figure 36A** is flat and circular, extending to cover the entire portion of the upper surface of the cylindrically shaped piston (3602), other embodiments could utilize other shapes and sizes for the active site region (3601) and the piston (3602). Additionally, a piston with a non-flat upper surface can be utilized to contour the shape of the active site region (3601), as shown in **Figure 36E,** wherein the piston (3602) has a rounded upper surface and the active site (3601) formed thereon has a rounded profile. Piston (3602) also may be fabricated from a suitable metal for improved heat sinking ability.

Another embodiment shown in **Figure 36F** utilizes a piston adapted to accept different active site regions of differing size or shape. As shown in **Figure 36F** an active site cap (3611) is held onto the piston (3602) by a pair of screws (3612). Alternatively, the cap may be affixed by a biocompatible glue, clips or other fasteners which are well known to those skilled in the art. RF energy is supplied to the active site through an RF connector (3613), which connects to an RF power supply line (3609). In this way a large active site region could be attached, by a screw or clip, to ablate larger areas of tissue while a small active site region could be used for the ablation of smaller volumes of tissue. Other shapes and sizes can be utilized to better adapt the probe to a specific application.

An alternate embodiment of the piston-type variable-height electrosurgical probe is shown in **Figure 36G**, wherein a thermal expansion element (3614) is located within the nonconductive portion of the probe (3603) and a piston (3602) with a conductive

active site area (3601) is located above and firmly attached to the thermal expansion element (3614). As the thermal expansion element expands, the piston moves in an upward direction, thereby increasing the height of the active site (3601) above the nonconductive portion of the probe (3603). Similarly, contraction by the thermal expansion element (3614) causes the piston (3602) to move downward, thereby lowering the height of the active site (3601). The thermal expansion element (3614) acts as an actuator to raise and lower the piston (3602). A separate power supply line (3615) is provided to the thermal expansion element (3614). The power supply line 3615 is coupled to a power supply (not shown). By varying the voltage applied to the element (3614), the surgeon can control the height of the active site (3601). It will be appreciated that element (3614) may comprise any well known material characterized by a useful coefficient of thermal expansion which enables the desired expansion/height to be achieved.

Figures 37A-37B show another embodiment of the present invention wherein an active site (3701) comprises a layer of conductive material attached to a balloon (3702). **Figure 37C** shows a side cross-sectional view of a probe (3703) shown in **Figures 37A-37B** and illustrates an RF energy line (3709), a pressure inlet line (3705), a pressure chamber (3704), and a circularly shaped hole (3706), which extends between the pressure chamber (3704) and the exterior of the probe (3703). The balloon (3702) is constructed from a layer of elastic material and is attached to the probe (3703) in such a manner as to form an airtight barrier over the hole (3706) between the pressure chamber (3704) and the exterior of the probe (3703). As shown in **Figure 37C**, the balloon (3702) is attached to the probe in such a manner that as pressure increases within the pressure chamber (3704) the balloon expands, thereby increasing the height of the active site above the nonconductive area of the probe (3703). Means for attaching the balloon (3702) to the edge of the hole (3706) include use of ultrasonic welding, laser welding or an adhesive or suitable mechanical clamping mechanism. For example, one embodiment of the present invention may utilize a ring-shaped clamp (not shown) which applies even pressure to hold the balloon (3702) securely in place and also provides an airtight seal between the balloon (3702) and the walls of the pressure chamber (3704). The ring-shaped clamp may be securely fastened to the nonconductive probe (3703) by four screws (3712) which screw from the exterior of the probe (3703).

Generally, several embodiments of the balloon-type variable height electrosurgical probe are shown in **Figures 37A-37F**. The active site (3701) shown in **Figure 37A-37B** is formed from a flexible layer of conductive material attached to the balloon (3702) by an adhesive. Alternatively, the conductive material of the active site (3701) can be sputter deposited on the balloon (3702) to form a flexible layer that expands with the balloon as the balloon is inflated, as shown in **Figure 37F**. In yet another embodiment of the present invention shown in **Figure 37D**, the active site (3701) is formed from strips of conductive material attached to the balloon (3702) by an adhesive. The sections of the balloon (3702) between the strips of conductive material are able to expand as pressure increases inside the balloon (3702). The spacing between the placement of the strips should be great enough to allow expansion of the balloon (3702) as pressure increases within the chamber (3704). To enable raising and lowering of the active site (3701). Each of the conductive strips is connected to an RF energy line (3709) which passes through the non-conductive portion of the probe (3703) from the handle of the probe. In each of the embodiments of the present invention shown in **Figures 37A-37F** the active site (3701) is connected to an RF energy line (3709).

Suitable materials for balloon construction include any elastic material such as a silicon, thermaplastic elastomers, rubber, neoprene or the same kind of materials used for an angioplasty balloon. The material chosen should be capable of expanding as pressure increases within the pressure chamber without allowing the gas or liquid within the pressure chamber to leak through the balloon material. Acceptable pressure ranges may be on the order of a few psi up to about 400 psi for specialized applications. Additionally, the adhesive material chosen to secure both the active site (3701) to the balloon (3702) and the balloon to the edge of the hole (3706) should be chosen such that it does not degrade the elasticity, structural integrity, or the ability of the balloon (3702) to seal against leaks from the pressure chamber (3704). While the cross sectional view of the probe (3703) shown in **Figure 37C** shows the balloon (3702) as a layer of flexible elastic material attached to the edge of the hole (3706), another embodiment shown in **Figure 37E** could utilize an entire balloon sac (3702) inserted into the pressure chamber (3706) and securely held within said pressure chamber (3706) in such a manner to prevent pressure from the pressure feed line (3705), connected to the opening of the balloon sac (3702), from escaping from the

pressure chamber (3706). Means for securely holding the balloon within the pressure chamber include the use of an adhesive which securely bonds the balloon to the walls of the pressure chamber (3704). Other securing means include a mechanical clamp holding the mouth of the balloon (3702) in place within the pressure chamber at the connection of the pressure chamber (3704) to the pressure line (3705). Various other clamping mechanisms are possible, which serve to securely anchor the balloon within the pressure chamber, thereby preventing the balloon from becoming dislodged from its position within the pressure chamber (3704).

In the embodiment shown in **Figure 37F** the active site (3701) is a layer of conductive material sputter deposited onto the balloon at low temperature to prevent melting or damaging the balloon (3702). Additionally, standard low temperature sputtering techniques can be employed to cool the balloon target during the sputtering process. Any biocompatible elastomeric material such as polyurethane or any material used for an angioplasty balloon can be used for the balloon, preferably with a thickness of approximately .001 inch. A layer of conductive material can be sputter deposited on the balloon to form the active site layer in accordance with conventional room temperature sputtering techniques which are well known. The important parameter is that the active site layer be thin enough to preserve the desired flexibility of the balloon. This process can be applied to all of the embodiments of the balloon-type variable-height electrosurgical probe.

The variable height active site electrosurgical probes shown in **Figures 36A-G** and **Figures 37A-F** are used by a surgeon to perform corneal tissue removal according to the procedure of the present invention. Once a probe, as shown in **Figures 36A-G** and **Figures 37A-F**, is inserted within the cornea, the surgeon may vary the height of the active site either by varying the pressure supplied to the probe through the air pressure line (3605) or (3705), by use of a pressure regulator (not shown), or by varying the current supplied to a thermal expansion element (3614) by two conductor power supply lines (3615) to the thermal expansion element.

The surgeon preferably is provided with a height v. pressure curve which is calibrated for each probe. This tells the surgeon precisely how much current to apply in order to achieve a desired height of the active site.

In accordance with an aspect of the invention, the height v. pressure curve may be embodied in a look up table in a microprocessor. As shown in **Figure 38** and, in accordance with standard control and active feedback techniques which are well known and can be implemented readily by one skilled in the art, a microprocessor 3800 and position sensor 3802 provide an active feedback control system. The active feedback control system indicates how far the probe 3804 is moved in terms of a height v. pressure curve (not shown) in response to a signal supplied from the position sensor 3802 which is coupled to the probe 3804. The feedback loop prevents the probe 3804 from being moved beyond a predetermined point to ensure a safe insertion point at all times.

The position sensor 3802 preferably comprises a transducer capable of critical linear displacement measurements. An example of such a displacement transducer is a differential variable reluctance transducer (DVRT) such as manufactured by MICROSTRAIN®, Inc. of Burlington, Vermont. Such DVRTs are extremely lightweight, small in size, and utilize flexible, elastic and biocompatible materials.

The displacement transducer/position sensor 3802 measures the position of the probe 3804. A conventional feedback control loop to the microprocessor 3800 then computes the change in pressure necessary to move the probe precisely to a desired position. The internal pressure of the corneal tissue amounts to about 60 mm of mercury. Thus a 1 psi increase in pressure supplied to the balloon as piston produces only a very small change in the height of the active site.

In **Figures 5-9 D**, a small nonconductive portion immediately adjacent to the active site is also raised above the larger nonconductive area. The raised nonconductive portion covers all or a part of the side area of the active site to limit the conductive area exposed to tissue. This prevents tissue removal from being caused by electrical energy from the covered side areas, thereby giving the surgeon greater assurance that tissue will be removed in a direction normal to the face of the active site and not in other, lateral directions spreading sideways from the raised active site. The insulation of the side areas also increases the current density associated with the face of the active site, providing more efficient tissue removal.

Figures 24 A-F illustrate an apparatus for positioning a circular electrosurgical probe to perform corneal tissue removal according to the procedure of the

present invention. The circular probe (2400) includes a circular contact end (2402) coupled to a support arm (2404) that is angled with respect to the plane of the circular contact end (2402). The angle may have a value of 0° to 900°. The angle is preferably between 0° and 800°, more preferably between 10° and 500° and most preferably about 340° (+/- 50°). This angle results in the support arm (2404) being generally perpendicular to the corneal surface when the circular contact end (2402) is introduced into the corneal stroma. This angle, although not absolutely critical, is desirable and has been found to prevent tearing of the epithelium during the corneal operation. The length of the support arm (2404) is sufficient so that the entire circular contact end is visible through the top of the barrel (2406) during use.

Figure 24B illustrates the circular contact end (2402) in greater detail. The contact end (2402) may be rectangular in cross-section as shown in **Figure 24B** or tapered on its smaller edge as shown in **Figure 24C**. The contact end may be of any convenient shape, including the rectangular cross-section of **Figure 24B** or the hexagonal cross-section of **Figure 24C** in which two opposite sides are longer than the remaining four.

The overall relationship of the sizes of the diameter of the arc (2408) of the contact end (2402) to the length of the barrel (2406) is desirably chosen so that the ratio of that length to the arc diameter is between 0.25:1 and 15:1; specifically between 0.4:1 and 1:1, at least about 1:1 and less than about 3:1; and at least about 3:1 but less than 15:1. These ratios allow easy manipulation by the surgeon. The contact end (2402) has two other physical parameters relevant to effective performance of the surgical procedure. Upon rotation of the barrel (2406), the contact end (2402) must move in a path which is substantially planar. The path of the contact end (2402) as it moves in the corneal intrastromal lamellar channel must not vary either up or down during the barrel (2406) rotation. The distance "a" shown in **Figure 24B** is chosen so that the contact end (2402) is centered about the axis (2410), which forms the center of the barrel (2406).

Similarly, the cone angle β (2412) is preferably 112° +/- 30°. Again, this permits the contact end (2402) to traverse a channel which is parallel to the lamella found in the corneal stroma. The cone angle β (2412) may, of course, vary a few degrees dependent on such variables as the size of the eye and the amount of correction required.

Preferably, all of the circular, disk-shaped, and washer-shaped probes described in this disclosure take on one of the cross-sectional shapes illustrated in **Figure 24B** or **24C**. The active sites of those probes can reside on the central flat portion and/or on the angled portion of the contact end of **Figure 24B** or **24C**.

Figure 24D is a side view of an insulated support base used in conjunction with the probe assembly of **Figure 24A**. The support base includes an annular circumcorneal vacuum ring (2450) and a cylindrical or central bore (2452) extending through the support base. The support base contains a viewing port (2454) to allow a surgeon to view the operational steps which take place at the corneal surface. The vacuum is brought in from a vacuum source line (2456) that is coupled to a vacuum pump (not shown). The vacuum ring (2450) is configured so that it meets with and seals to the front of the eye, rendering the support base relatively immobile when the support base is applied to the front of the eye and a suitable vacuum is applied to the vacuum source line (2456). The vacuum chamber forms an annular vacuum space across the front of the eye.

Figure 24E shows a bottom view of the support base in which the circumcorneal vacuum ring (2450) may be clearly viewed. The vacuum ring (2450) is made up of an inner wall (2458) terminating on its inside by the central bore (2452). The central bore (2452) is at least large enough to see the entirety of the circular contact end (2402). The central bore (2452) has an axis which substantially coincides with the axis of the circular contact end (2402). The central bore (2452) is desirably a length such that the ratio of the bore's length to its diameter is between 0.25:1 and 15:1; specifically between 0.4:1 and 1:1, at least about 1:1 and less than about 3:1; or at least about 3:1 up to about 15:1. Preferably, the ratio is about 2.5:1. This sizing allows easy manipulation by the surgeon. The outer vacuum ring wall (2460) desirably forms the outside of the support base. Interior to the vacuum ring (2450) may be one or more ridges (2462) which extend down to the corneal surface when the support base is attached to the eye. These ridges may be made of conductive material, while the surrounding support base structure, such as the inner wall (2458) and outer wall (2460), are made of insulating material. The ridges (2462) may be coupled to an electrosurgical generator (not shown). Using this configuration, the ridges (2462) may act as return electrodes when operating in sesquipolar mode. These return electrodes may be positioned to rest on the sclera or translimbal region of the eye.

Figure 24F shows an alternative arrangement of return electrodes comprised of radial vanes (2464) that extend downward through the vacuum ring (2450) to make contact with the sclera or translimbal region.

Figures 25-34 A and **B** show top (A) and side (B) views of circular (substantially hook-shaped) probes having inwardly-directed contact end portions suitable for use in the schematic procedure described above. **Figure 35** illustrates a complementary pair of probes used to modify an annular 360 degree channel of tissue. One probe of the pair is inserted and rotated in one direction to modify tissue, and then removed. The complementary probe is then inserted and rotated in the other direction to modify the remaining tissue in the channel, and then removed. Those skilled in the art will recognize that the circular probes of **Figures 25-34** may be employed as part of a complementary set, and may be easily modified to subtend any angle of a circle, not just 180 degrees as shown. The complementary probe subtends an angle of the circle equal to 360 degrees less the radial angle of the first probe, so that a full 360 degree volume of tissue can be ablated or desiccated. As described below, a complementary probe set to complete a 360 degree path may be required for treatment of hyperopia and myopia, but not necessarily for astigmatism.

These configurations allow high current density to be achieved with relatively low power due to the relatively small area of the active site. They are particularly appropriate as an alternative to the disc and washer shaped probes shown in **Figures 20** and **21**. In comparison, the latter probes require a higher power to achieve the same current density because of the larger area of their active sites. Further, the access site incision required for insertion of the probes of **Figure 25-32** is smaller, resulting in less trauma to the eye during the procedure.

Figures 25 A and **B** show a circular probe (265) having an inwardly-directed contact end portion (269) with a single active site (267). The active site shown in 25B may be open (uninsulated) only on top, or open on the top and the leading side, but insulated on the trailing side (as shown). In general, the sides and the top of the probes described herein may be insulated or open in different combinations. The leading and trailing sides are defined by the direction of rotation, here counterclockwise. The probe (265) includes a shaft (266) and an active site (267). The probe has an inner diameter of

approximately 6.5 mm and an outer diameter of approximately 8.5 mm. The inwardly-directed contact end portion is directed along the radial axis of the circular ring. The single source of RF energy (268) is fed in through the insulative contact end (266) making up the probe (265).

Figures 26A and **26B** show a circular probe (270) having an inwardly-directed contact end portion with a single active site (271) at the tip. Again, the single source of RF energy (272) is fed in through the insulator making up the probe.

Figures 27A and **27B** show a circular probe (275) having an inwardly-directed contact end portion with a single active site (276) extending the length of the inwardly-directed contact end portion of the probe. The active site can be of varying thickness, take on different shapes, and be angled within the insulated inwardly-directed portion. The active site shown in **Figure 27** is shown as a thin wire to achieve high current density, but may be broader. The active site may also contain bends instead of being straight, or may be angled within the insulated inwardly-directed portion as shown in **Figure 33**. Rotation of the active site during activation of the probe will remove a disk of corneal tissue for those probes where the active site extends all the way to the center of rotation. Once more, the single source of RF energy (277) is fed through the insulator making up the probe.

Figures 28A and **28B** show a circular probe (280) having an inwardly-directed contact end portion with two active sites (281) that operate in bipolar fashion near the tip of the inwardly-directed contact end portion. Two sources of RF energy (282 and 283) are fed in through the insulator making up the probe.

Figures 29 A and **B** show a circular probe (284) having an inwardly-directed contact end portion with a raised single active site (285) on the leading side with a raised insulated backstop (286) on the trailing side. **Figure 29** shows the active site raised with an open top (287), although this top side can also be insulated in an alternative embodiment. A single source of RF energy (288) is fed in through the probe.

Figures 30 A and **B** show a circular probe (289) having an inwardly-directed contact end portion with a single active site (290) located on the leading edge of the probe. As **Figure 30B** shows, the active site is open only on the leading side and not on the top or trailing sides.

Probe (291) in **Figure 31** is an alternative embodiment of probe (265) of **Figure 25** where the inwardly-directed contact end portion (293) is angled with respect to the radial axis of the circular portion (295). Note that the inwardly-directed portion may alternatively be angled into the area that is a reflection about the radius from the area in which the inwardly-directed portion of **Figure 31** lies. All of the active site configurations of probes (270), (275), (280), (284), (289), (298), (500), and (505) can be angled in a similar manner.

Probe (298) in **Figure 32** is another embodiment of probe (265) illustrating that the inwardly-directed contact end portion (296) can be of variable length. Rotation of this active site during activation of the probe will remove a wide annulus of corneal tissue.

Figures 33 A and **B** show an alternative embodiment of **Figures 27 A** and **B** where the active site (501) is angled rather than parallel to the sides of the inwardly-directed contact end portion.

Figures 34 A and **B** show a circular probe (505) having an inwardly-directed contact end portion with two active sites (506 and 507) which may operate in a time multiplexed fashion. Two sources of RF energy (508 and 509) are fed in through the insulator making up the probe. In one operational mode, active site (506) is activated during forward (counterclockwise in this example) rotation of the probe while active site (507) is off. During backward (clockwise) rotation, active site (507) is activated while active site (506) is off. The use of two smaller active sites rather one larger one allows for a higher current density to be achieved with relatively low power due to the smaller area of each active site.

Figures 25-28 C and **D** show alternative side views of inwardly-directed portions of circular probes with inwardly-directed contact ends where the active sites applied to tissue are raised above a substantial portion of the nonconductive area of the probe. The design and purpose of the raised active sites are the same as that for the circular probes described above. In **Figures 25-28 D**, a small nonconductive portion immediately adjacent to the active site is raised on two sides of the active site to limit the conductive area exposed to the tissue. The insulation can also cover the trailing side of the active site and/or the top of the active site to reduce the area further, leaving only the leading side exposed. Alternatively, all sides can be insulated to leave only the top side exposed. This

insulation around the active site ensures tissue removal normal only to the open faces of the active site and not in undesired lateral directions. The insulation also increases the current density associated with the open faces of the active site.

Figures 12-19 A and **B** show top (A) and side (B) views of straight electrosurgical probes suitable for use in the schematic procedure described above. **Figures 12A** and **B** show a straight RF surgical probe (300) with a single active site (302) extending along the length of the probe. A single source of RF energy (304) is fed through the probe. **Figures 13A** and **B** show a straight RF electrosurgical probe (310) with two active sites (312) extending along the length of the probe that operate in bipolar fashion. Two sources of RF energy (314 and 316) are fed in through the insulator (318) making up the probe.

Figures 14-19 A and **B** show other straight RF electrosurgical probes with single active sites near the tips of the probes. A single source of RF energy is fed in through each probe. **Figures 14 A** and **B** show the active site (322) to be located near the tip of the probe (320) and on top of the probe such that the active site is raised and pointed in the retracting direction of the probe. **Figures 15A** and **B** show the active site (332) similarly located near the tip of the probe. The end of the probe is raised and the active site (332) is located on the raised part of the tip pointing backwards, the active site being exposed on two sides. **Figures 16A** and **B** similarly show the active site (342) raised at the end of the probe pointing backwards (340), but the active site is imbedded in the insulating curve of the probe, thereby exposing the active site on one side only. **Figures 17A** and **B** show the active site (352) at the tip of a straight probe (350), the active site being exposed on one side on the tip portion alone. **Figures 18A** and **B** show the active site (362) near the end of a straight probe (360). The probe is broadened at the active site.

Figures 19A and **B** again show a straight RF electrosurgical probe (370) with a curved tip, with the active site (372) again raised and pointing backwards and slightly upwards the active site being exposed on one side on the tip portion alone. However, in this embodiment the active site is angled such that a portion (374) of the active site (372) extends beyond the curved tip. In this design, the ablation or desiccation takes place either as the device is pushed forward or as it is pulled backwards, or retracted from the lamellar separation channel.

Upon exposure to tissue and electrode activation, the active site will vaporize or desiccate the tissue. It may be desirable to provide a second lamellar channel to allow for the relief of gases produced by the probe when used in the ablation mode or to incorporate grooves in the probe portions that insert into the tissue to allow the escape of gases so produced.

Figures 12-14C and **D** are side views of the probes of **Figures 12-14A**, respectively, for alternative embodiments. In **Figures 12-14C**, the active sites are raised above the larger nonconductive areas. In **Figures 12-14D**, a small nonconductive portion immediately adjacent the active site is also raised above the larger nonconductive area. **Figures 17C** and **D** are top views of the probe of **Figure 17A** for an alternative embodiment. In **Figure 17C**, the active site is raised above the larger nonconductive area. In **Figure 17D**, a small nonconductive portion immediately adjacent the active site is also raised above the larger nonconductive area.

Figures 20 and **21 A** and **B** show top (A) and side (B) views of RF electrosurgical disc and washer probes (400 and 410 respectively). A single RF energy source is fed through each probe. The disc probe (400) is a circular probe with a circular active site (410). The washer probe (410) is a circular probe with a circular active site (412) with a hollow middle (414). Each of these probes may have a flat surface as shown in **Figures 20A** and **21A** or may be curved to conform to the curvature of the cornea. The disc probe may have a wire loop surface (415) as shown in **Figure 21C**.

Figures 20C, 21D and **21F** are side sectional views of the probes of **Figures 20A, 21A** and **21C**, respectively, for alternative embodiments. In **Figures 20C, 21D** and **21F**, the active sites are raised above the larger nonconductive areas. **Figures 20D, 21E** and **21G** are side sectional views of the probes of **Figures 20A, 21A** and **21C**, respectively, for alternative embodiments. In **Figures 20D, 21E** and **21G**, a small nonconductive portion immediately adjacent the active site is also raised above the larger nonconductive area.

Figures 22A and **B** illustrate the straight probe of **Figure 14D** and the disc probe of **Figure 20A**, respectively, in a sesquipolar configuration for removing tissue from a portion of the corneal mass (2200) near the center of the visual axis. Each probe includes a handle (2202) that is angled with respect to the contact end portion (2204) of the probe.

An active lead (2206) from an electrosurgical generator (2208) runs into the handle (2202) for connection to the active site (2210). The return electrode (2212) may be placed remotely on the body, e.g., onto a shaved area on the back of the patient's head. The return electrode (2212) is connected to the electrosurgical generator (2208) through a return lead (2214). Alternatively, the return electrode (2212) may be placed on the exterior of the cornea or onto the sclera or translimbal region (2216), as shown. The return electrode (2212) may simply rest in place or be held by a vacuum attachment cavity built into the electrode. Because of its significantly higher area as compared to the active tissue contacting site, the return electrode (2212) does not generate much heat. Those skilled in the art will understand that any of the probes described herein may use a handle, whether angled or not, for the convenience of the surgeon. Further, except for the bipolar probes, any of the probes of the invention may be arranged in the sesquipolar configuration of **Figures 22A** and **B**.

The above described probes are useful in the particular examples discussed below. The examples are illustrative only and are not intended to limit the scope of the invention.

The following examples are intended to describe a particular embodiment of the invention but are in no way intended to limit the invention in any manner.

Examples

Example 1 - The Correction of Astigmatism

In order to correct the astigmatic eye shown in **Figures 4A** and **4C** such that it becomes more similar to that shown in **Figures 4B** and **4D**, a process similar to that described above with regard to **Figures 3A-3D** is carried out. As shown in **Figures 23A** and **23C**, radial or circumferential partial depth incisions (500) are made in the periphery of the cornea. A lamellar separator is inserted to create a zone of separated lamellae (502) and (504) for the insertion of the electrical probe.

Two different approaches are possible to correct the astigmatic eye. In the first approach shown in **Figure 23C** the radial partial depth incisions and radial zone of separated lamellae will be formed beneath the astigmatic axis (506). Following separation of the lamellar tissue, one of the straight RF probes shown in **Figures 14-19 A** and **B** is

inserted through the partial depth incision (500). The probe is then activated to change the paracentral corneal volume (508), that is the volume near the center of the cornea, by ablation of the tissue under the figure-8-shaped astigmatism shown in **Figure 23A** and **23C**. The choice of RF probe design is dependent on the amount of tissue to be ablated. Once ablation is completed, the probe is withdrawn. Relief cuts on the anterior cornea may be necessary as described above to allow the surface of the cornea to conform to the underlying tissue removal. In this way, the steep astigmatic axis is flattened such that the cornea becomes reasonable symmetrical and spherical.

A second approach to the treatment of an astigmatic eye is to steepen the flat astigmatic axis as shown in **Figure 23A**. In this approach, the lamellar separation zone will be formed in the periphery of the cornea (502). The partial depth incision (500) is placed in the corneal periphery, beneath the astigmatic axis. Following separation of the lamellar tissue, one of the circular RF probes shown in **Figures 5, 6, 8, 9, 10**, and **11 A** and **B**, probes (200), (210), (220), (230), (240), (250) and (260) respectively, is inserted through the partial depth incision (500). The probe is then activated to change the volume by desiccation (probes (200), (210), (230), (240), (250) or (260)) or by ablation (probes (210), (240), (250), or (260)) of the tissue (501) under the flat axis of astigmatism axis (507) as shown in **Figure 23A**. Thus some probe configurations can be used either in the ablate or in the desiccation mode. Probe (200) is operated by inserting it into the lamellar tissue, activating it, deactivating it, and then removing it. Probes (210), (230), (240), (250), and (260) are operated by insertion into the lamellar tissue, activation, deactivation, rotation to a second position to be desiccated or ablated, activation, and then repeating this procedure until the desired tissue volume has been modified. Again, the choice of RF probe design is dependent on the amount of tissue to be ablated or desiccated. Once ablation or desiccation is completed, the probe is withdrawn. Relief cuts to the anterior cornea may be necessary as described above to allow the surface of the cornea to conform to the underlying tissue modification. In this way, the flat, astigmatic axis (507) is steepened such that the cornea becomes reasonably symmetrical and spherical.

An alternative to this second approach is to use a circular probe with an inwardly-directed contact end portion. Following separation of the lamellar tissue, one of the probes in **Figures 25-34** is inserted through the partial depth incision (500). The probes

can be used to change the volume by desiccation or ablation of the tissue (501) under the flat axis of astigmatism axis (507) as shown in **Figure 23A**. The probes are operated by insertion into the lamellar tissue, activation, deactivation, rotation to a second position to be desiccated or ablated, activation, and then repeating this procedure until the desired tissue volume has been modified. Again, the choice of RF probe design is dependent on the amount of tissue to be ablated or desiccated. Once ablation or desiccation is completed, the probe is withdrawn. Because astigmatic correction typically does not require tissue modification along a full 360 degrees, modification with one probe, rather than a complementary pair, may be sufficient. Again, relief cuts on the anterior corneal surface may be necessary as described above to allow the surface of the cornea to conform to the underlying tissue removal.

Example 2 - The Correction of Hyperopia

In order to correct hyperopia a process similar to that described above with regard to **Figures 3A-3D** is carried out. As shown in **Figures 23B, 23D** and **23E**, radial or circumferential partial depth incisions (510) are made in the periphery of the cornea. A lamellar separator is inserted to create a lamellar pathway (512) for the insertion of the electrical probe.

Two different approaches are possible to correct the hyperopic eye. In the first approach, shown in **Figure 23B**, partial depth incisions (510) are made in the peripheral cornea and a circumferential lamellar separation zone (512) will be formed beneath the corneal surface.

A circular intrastromal channel may first be made using the apparatus of US Patent No. 5,403,335, issued to Loomas *et al.*, and assigned to the assignee of the present invention. That patent is incorporated by reference herein in its entirety. During the creation of the channel, the support base of **Figures 24D-F** may be substituted for the support base of the Loomas patent so as to provide a sesquipolar return electrode for use during the later stage of tissue volume reduction.

Following separation of the lamellar tissue, one of the circular probes or one of the circular probes with an inwardly-directed contact end portion described herein is inserted through the partial depth incision (512). In particular, the assembly of **Figures**

24A-D may be employed. If using the latter type of probe, the radial inwardly-directed contact end portion is first inserted without using the support base shown in **Figure 24D.** The support base is then slipped over the barrel, or alternatively, the procedure is performed freehand. For the former probe type, the base may be in place over the eye during initial insertion. Once the guide is in place, the barrel is rotated and the rest of the circular probe enters the cornea. The probe is then activated to change the volume by ablation or desiccation of the tissue (514) in the channel. This procedure may also be employed to correct myopia or astigmatism, using the probes and motions appropriate for those corrections. The choice of RF probe design is dependent on the amount and location of tissue to be ablated or desiccated.

Circular probes (210), (220), (230), (240), (250) and (260) will allow for desiccation of the channel. Circular probe (220) is operated by inserting it into the lamellar tissue, activating it, deactivating it, and then removing it. The other circular probes are operated by inserting them into the lamellar tissue, activating, deactivating, rotating to a second position to be ablated, activating, deactivating and repeating this process until the entire channel is desiccated, and then removing it. Circular probes (210), (240), (250) and (260) will allow for ablation of the channel. The probes are operated by insertion into the lamellar tissue, activation, deactivation, rotation to a second position to be ablated, activation, and repeating until the entire channel is ablated, followed by removal of the probe. Circular probes (250) and (260) can also be operated by complete insertion into the lamellar tissue, activation, deactivation, pulling partially back out of the tissue to a second position to be ablated, activation, deactivation and repetition of this process until the entire channel is ablated, followed by removal of the probe. Again, relief cuts in the anterior of the cornea may be necessary as described above to allow the surface of the cornea to conform to the underlying tissue removal. In this way, the central corneal surface is steepened such that the cornea curvature is improved.

Circular probes with inwardly-directed contact end portions (265), (284), (289), (291), and (298), for example, will also allow for either desiccation or ablation of the channel to correct for hyperopia. The other probes may also be used if modified to remove an annulus of tissue for hyperopic correction. The probes are operated using a clockwise/counterclockwise set. First, one probe is inserted into the lamellar tissue,

activated, deactivated, rotated to a second position to be ablated or desiccated, activated, and repeated until half the circular channel is ablated or desiccated, followed by removal of the probe. The complementary probe is then inserted into the lamellar tissue, activated, deactivated, rotated to a second position in the opposite direction than that of the first probe to be ablated or desiccated, activated, and repeated until the second half of the circular channel is ablated or desiccated, followed by removal of the probe. Again, relief cuts in the anterior of the cornea may be necessary as described above to allow the surface of the cornea to conform to the underlying tissue removal. In this way, the central corneal surface is steepened such that the cornea curvature is improved.

A second approach to the treatment of a hyperopic eye is to use a straight RF probe. In this second approach 2 or more partial depth incisions (510) are made in the periphery and 2 or more radial lamellar separation zones are formed as shown in **Figures 23D** and **23E**. Following separation of the lamellar tissue, one of the straight RF probes shown in **Figures 12-19 A** and **B** is inserted through each partial depth incision (510) in the lamellar separation zones (512) and (514). The probe is then activated to change the volume by ablation or desiccation of the tissue in the channel. The choice of RF probe design is dependent on the amount of tissue to be ablated or desiccated. Probes (300), (310), (320), (330), (340), (350), (360) and (370) will allow for desiccation of the channel. Probes (300) and (310) are operated by insertion into the lamellar tissue, activation, deactivation, and then removal. Probes (320), (330), (340), (350), (360) and (370) are operated by inserting into the lamellar tissue, activating, deactivating, moving to a second position to be ablated, activating, deactivating and repeating this process until enough of the channel is desiccated, and then removing the probe. In this way the tissue desiccated can either form a continuous path (516) or can be interrupted points along the radial lamellar separation channel (518). Probes (320)-(370) will allow for ablation of corneal volume inside the radial lamellar separation channel. Probes (320), (340), (350), (360) and (370) are operated by insertion into the lamellar tissue, activation, deactivation, moving it further into the tissue to a second position to be ablated, activation, and repeating until the entire channel is ablated, and then removal. The same probes can also be operated by complete insertion into the lamellar separation channel, activation, deactivation, pulling back out of the tissue channel to a second position to be ablated, activation, deactivation

and repetition of the process until the enough of the channel is ablated, followed by removal of the probe. Again, relief cuts may be necessary in the anterior cornea as described above to allow the surface of the cornea to conform to the underlying tissue removal. In this way, the corneal surface is steepened centrally such that the corneal curvature is improved.

Example 3 - The Correction of Myopia

In order to correct myopia the process similar to that described above with regard to **Figures 3A-3D** is carried out. As shown in **Figures 23F** and **23G**, radial or circumferential partial depth incisions (520) are made in the periphery of the cornea. A lamellar separator is inserted to create a radial lamellar separation channel (522) toward the center of the pupil for the insertion of the electrical probe.

For correction of myopia, the lamellar path (522) will be formed under or near the central or paracentral portion of the cornea. Following separation of the lamellar tissue, one of the straight RF probes shown in **Figures 14-19 A** and **B** or the disc or washer probes shown in **Figures 20-21 A** and **B** is inserted through the peripheral partial depth incision (520) into the lamellar separation channel (522). The probe is then activated to change the volume by ablation of the tissue in the channel, the volume change (524) resulting from the use of the disc-shaped probe (400) is shown in **Figure 23F** and volume change (526) resulting from the use of the washer-shaped probe (410) is shown in **Figure 23G**. The choice of RF probe design is dependent on the amount of tissue to be ablated. Probes (320)-(370) will allow for ablation of the channel. The probes are operated by insertion into the lamellar tissue, activation, deactivation, advancing the probe into the channel to a second position to be ablated, activation, deactivation, repeating the process until the entire channel is ablated, and then the probe is removed. The probes can also be operated by complete insertion into the lamellar separation channel, activation, deactivation, pulling out of the channel to a second position to be ablated, activation, deactivation and repeating the process until the entire channel is ablated, and then the process is removed. Probes (400) and (410) are operated by insertion into the lamellar separation channel (522), activation, deactivation and removal from the channel. Again, relief cuts in the anterior cornea may be necessary as described above to allow the surface

of the cornea to conform to the underlying tissue removal. In this way, the corneal surface in the central corneal area is flattened such that the corneal curvature is improved.

A second approach to the treatment of a myopic eye is to use a complementary pair of circular probes with inwardly-directed contact end portions. As with use of the straight probes, a lamellar separator is first inserted to create a radial lamellar separation channel toward the center of the pupil for the insertion of the electrical probe. Following separation of the lamellar tissue, probe (270), (275), (280), (500), or (505), for example, is inserted through the peripheral partial depth incision into the lamellar separation channel. Other probes may be used if modified to remove tissue from a central corneal area to correct myopia. The probe is operated by activation, deactivation, advancement of the probe into the channel to a second position to be ablated or desiccated, activation, deactivation, and repeating the process until the radial inwardly-directed contact end portion has rotated 180 degrees and half the radial channel is ablated or desiccated. The probe is then removed and the complementary probe is inserted and operated in the same manner as the first probe, but rotated 180 degrees in the opposite direction so that the entire radial channel is ablated or desiccated as shown in **Figure 23F**. Again, relief cuts in the anterior cornea may be necessary as described above to allow the surface of the cornea to conform to the underlying tissue removal. In this way, the corneal surface in the central corneal area is flattened such that the corneal curvature is improved.

The foregoing examples of procedures and devices according to the present invention are only representative and are not meant to be in any manner limiting. Other embodiments, areas of application, methods of use of the present invention, within the scope of the claims appended hereto, will be evident to those skilled in this art. Other embodiments of the procedures without the scope of the claims but within the spirit of invention described herein are considered to be equivalent to those procedures and devices claimed.

WHAT IS CLAIMED IS:

1. An electrosurgical probe for insertion into a corneal mass comprising:

a housing having a support portion and a contact end;

at least one active tissue contact site comprising a conductive material and disposed at the contact end of the housing, each of the at least one active site having a height, the height being selectively adjustable.

2. The electrosurgical probe of claim 1, wherein the height of the at least one active site is adjustable in response to pressure applied to the active site.

3. The electrosurgical probe of claim 2, the at least one active site comprising a flexible conductive material, the support portion including a passage for operably coupling the flexible material to a pressure supply, wherein the height of the active site varies in response to changes in pressure from the pressure supply.

4. The electrosurgical probe of claim 1, further comprising:

a moveable piston disposed within the contact end of the housing and having the at least one active site attached thereon, wherein the movable piston moves to adjust the height of the at least one active site; and

an actuator for moving the piston to change the height of the at least one active site.

5. The electrosurgical probe of claim 4, wherein the actuator includes a pressure chamber located within the contact end and wherein the moveable piston moves in response to changes in pressure within the pressure chamber.

6. The electrosurgical probe of claim 4, further comprising a spring for biasing the movable piston in a direction away from the at least one active site.

7. The electrosurgical probe of claim 4, wherein the at least one active site is located on an exterior surface of the moveable piston.

8. The electrosurgical probe of claim 7, wherein at least a portion of the exterior surface of the movable piston is rounded.

9. The electrosurgical probe of claim 4, wherein the at least one active site is removably attached to the movable piston.

10. The electrosurgical probe of claim 1, further comprising a pressure chamber located within the contact end of the housing and an expandable material expandable in response to pressure changes within the pressure chamber, wherein the at least one active site is attached to the expandable material.

11. The electrosurgical probe of claim 10, wherein the at least one active site comprises a conductive layer attached to the expandable material by an adhesive material.

12. The electrosurgical probe of claim 11, wherein the at least one active site comprises a layer of conductive material sputter deposited onto the expandable material.

13. The electrosurgical probe of claim 12, wherein the at least one active site is arranged to allow expansion of said expandable material.

14. The electrosurgical probe of claim 1, wherein the contact end of the housing comprises a nonconductive material.

15. The electrosurgical probe of claim 1, wherein the at least one active site is electrically coupled to a radio frequency energy line for delivery of radio frequency energy to the at least one active site.

16. The electrosurgical probe of claim 1, further comprising a thermal expansion element disposed in the contact end of the housing, wherein thermal expansion or compression of the element is controllable to selectively adjust the height of the at least one active site.

17. An electrosurgical system for introduction into a corneal mass comprising:

a probe having a housing including a contact end and a support;

at least one active surface area comprising a conductive material and disposed at the contact end of the housing, each of the at least one active area having a height, the height being selectively adjustable;

a sensor operably coupled to at least one of the contact end and the active area for generating one or more signals in response to a parameter; and

a microprocessor for receiving the one or more signals from the sensor and for generating an output indicative of the height of the active area.

18. The electrosurgical system of claim 17, wherein the microprocessor includes an active feedback loop for maintaining the active site at a predetermined height.

19. The electrosurgical system of claim 17, wherein the microprocessor includes a look-up table for corresponding the one or more signals to the height of the at least one active area.

20. A method for altering the shape of the cornea, comprising:

inserting an electrosurgical probe into an intrastromal channel, the probe comprising a conductive active region; and

applying a current to the electrosurgical probe to activate the active region of the electrosurgical probe to selectively change the volume of the cornea by removing and/or shrinking portions thereof.

21. The method of claim 20, wherein applying a current to the electrosurgical probe delivers radio frequency energy to the conductive active region.

22. The method of claim 20, wherein the radio frequency energy is delivered is pulsed or continuous, non-pulsed.

23. The method of claim 20, further comprising removing the electrosurgical probe from the cornea.

24. The method of claim 20, further comprising forming a corneal surface incision, wherein said electrosurgical probe is inserted into the corneal tissue though one of the at least one corneal surface incision.

25. The method of claim 20, further comprising forming one or more corneal surface relief incisions.

26. The method of claim 20, wherein activating the electrosurgical probe causes vaporization of the regions of the cornea adjacent to the active region of the probe.

27. The method of claim 20, wherein activating the electrosurgical probe causes desiccation such that the region of the cornea adjacent to the active region of the probe shrinks or necroses.

28. The method of claim 20, wherein the electrosurgical probe has a desiccation mode and an ablation mode, wherein activation in the desiccation mode causes desiccation such that the region of the cornea adjacent to the active region of the probe shrinks or necroses and wherein activation in the ablation mode causes causes vaporization of the regions of the cornea adjacent to the active region of the probe.

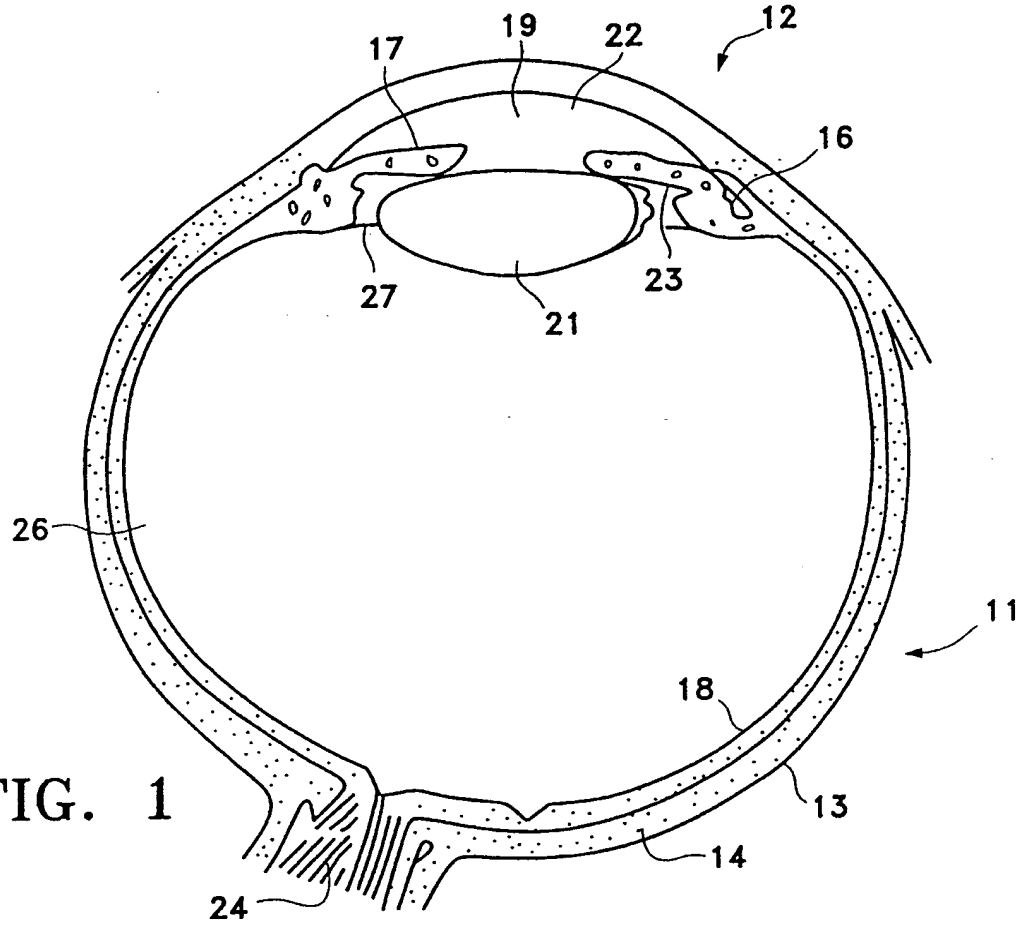

FIG. 1

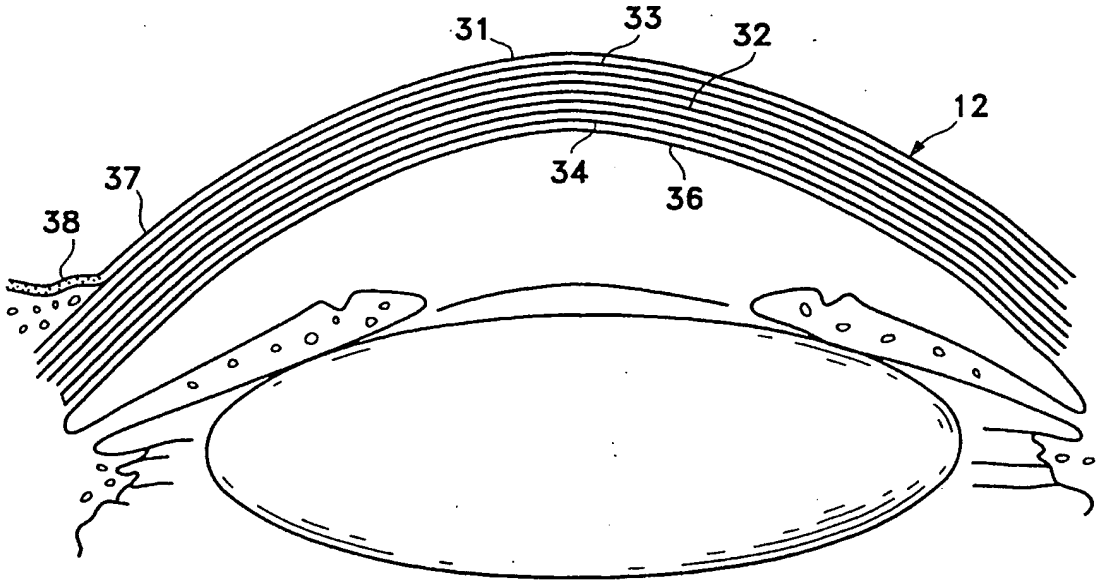

FIG. 2

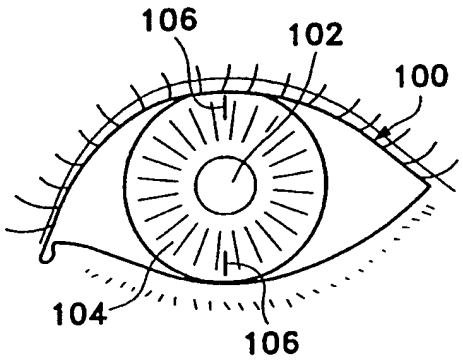

Fig. 3A

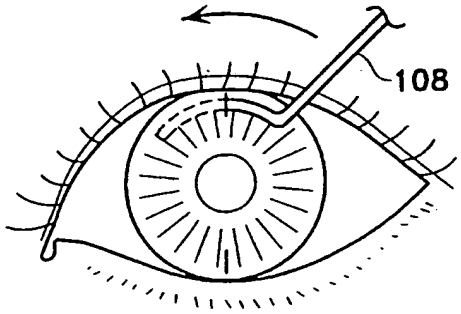

Fig. 3B

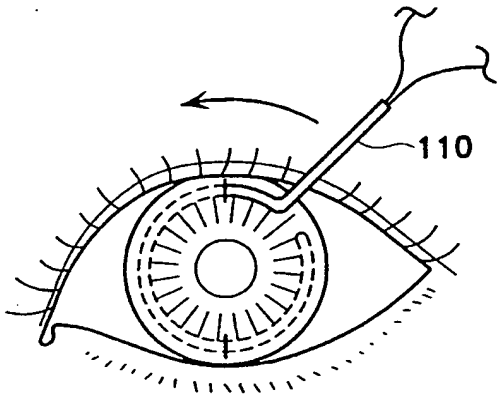

Fig. 3C

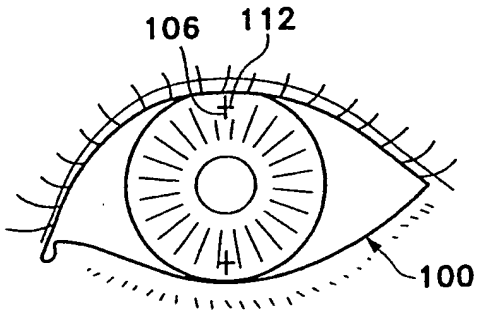

Fig. 3D

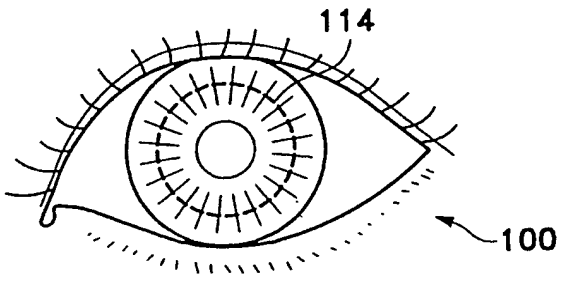

Fig. 3E

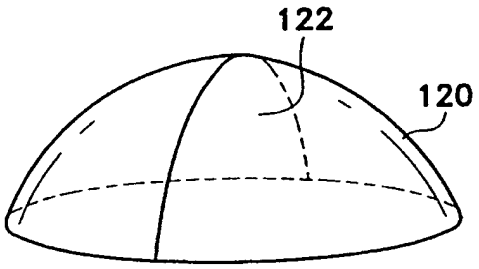

Fig. 4A

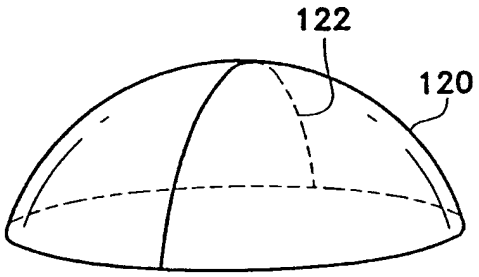

Fig. 4B

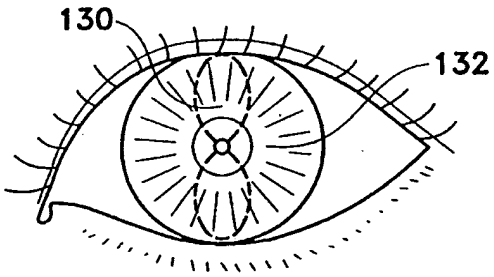

Fig. 4C

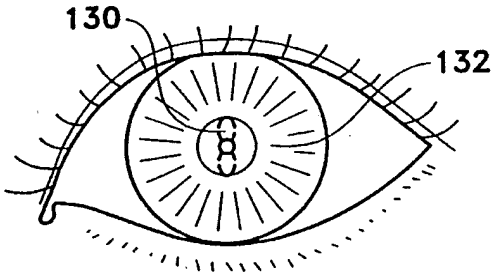

Fig. 4D

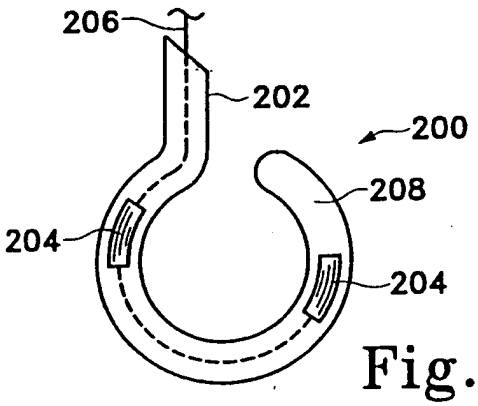

Fig. 5A

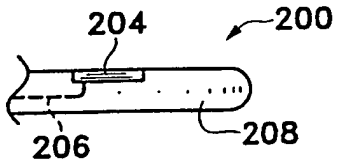

Fig. 5B

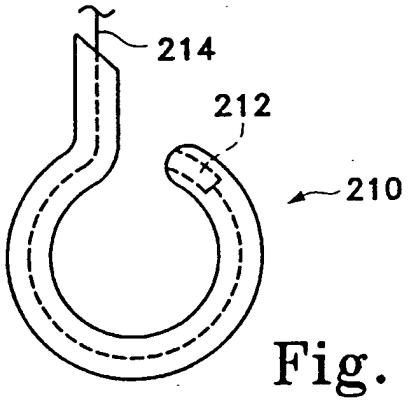

Fig. 6A

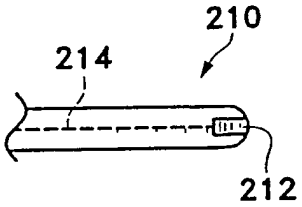

Fig. 6B

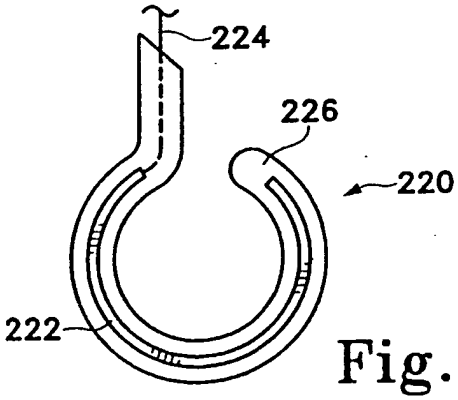

Fig. 7A

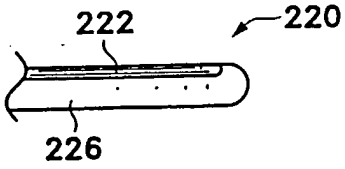

Fig. 7B

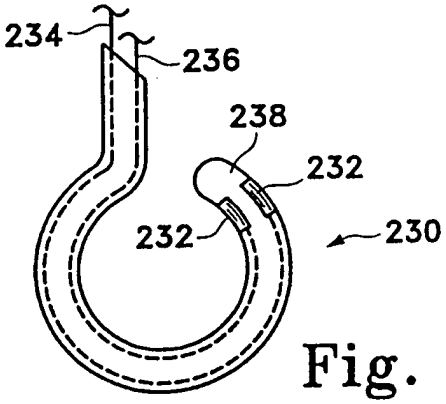

Fig. 8A

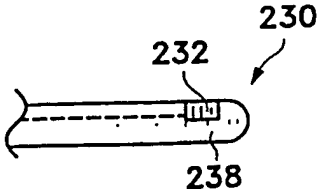

Fig. 8B

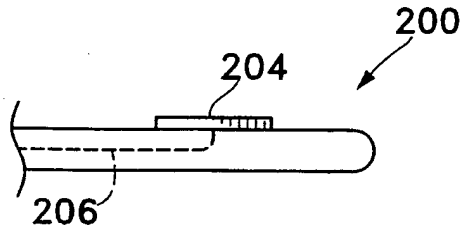

FIG. 5C

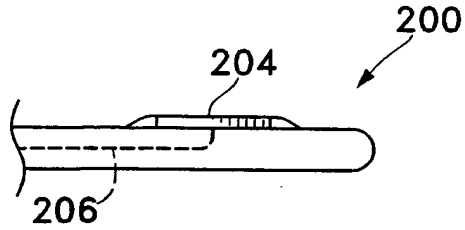

FIG. 5D

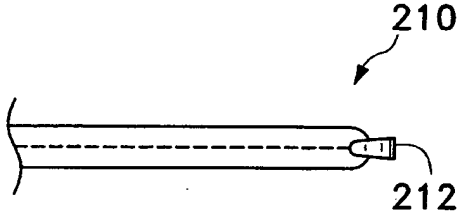

FIG. 6C

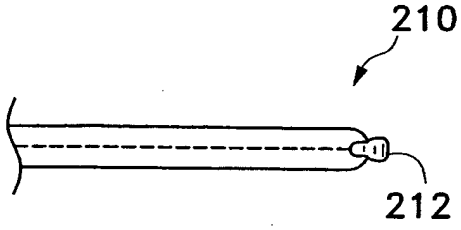

FIG. 6D

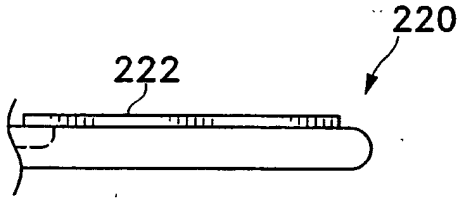

FIG. 7C

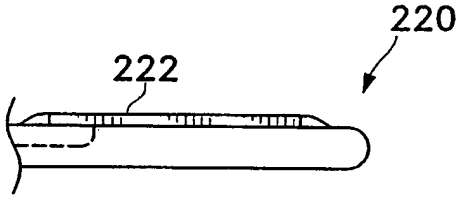

FIG. 7D

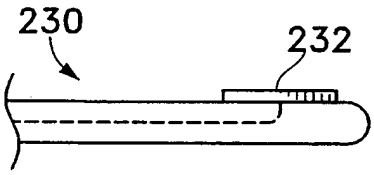

FIG. 8C

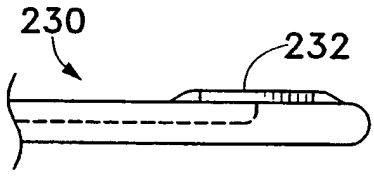

FIG. 8D

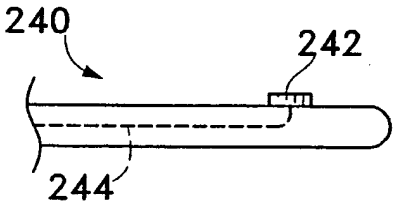

FIG. 9C

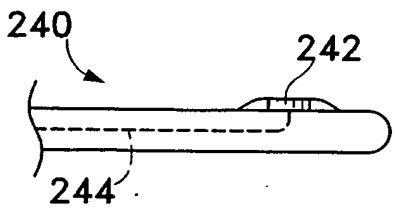

FIG. 9D

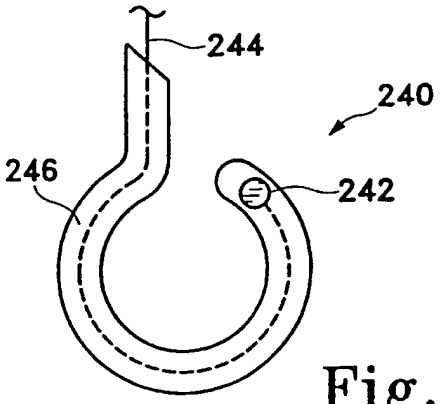

Fig. 9A

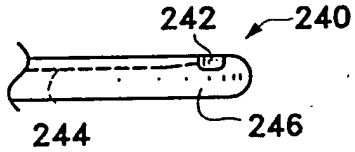

Fig. 9B

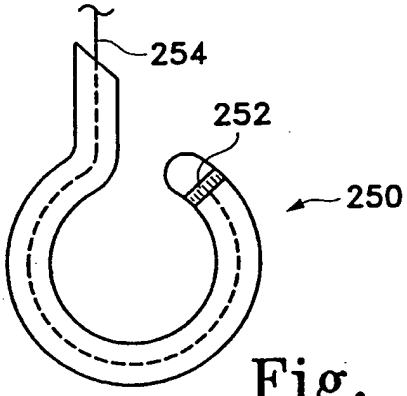

Fig. 10A

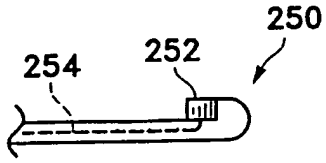

Fig. 10B

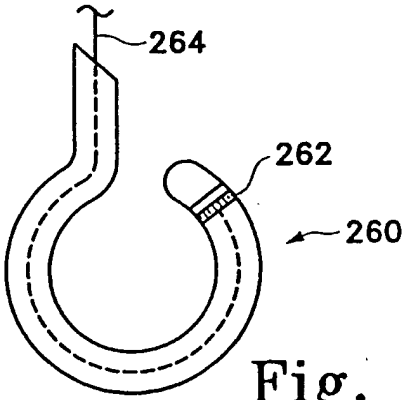

Fig. 11A

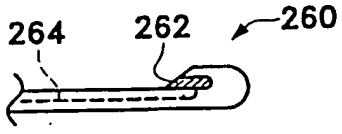

Fig. 11B

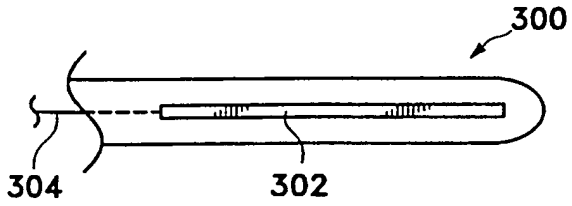

Fig. 12A

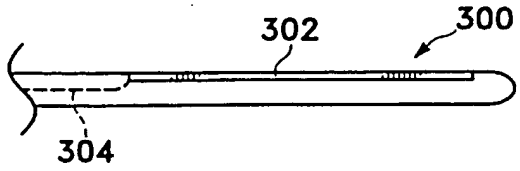

Fig. 12B

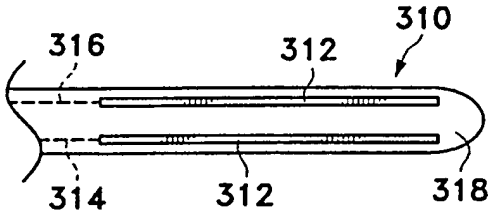

Fig. 13A

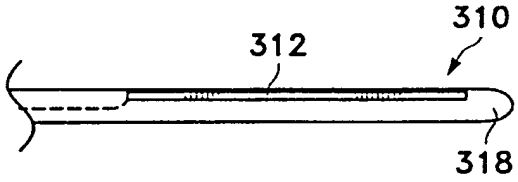

Fig. 13B

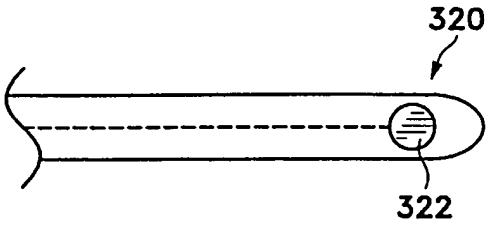

Fig. 14A

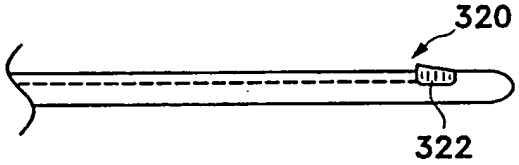

Fig. 14B

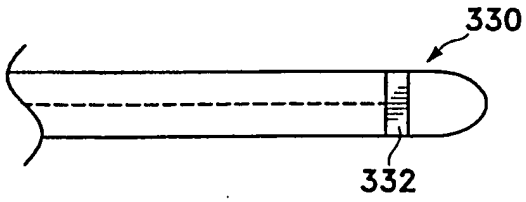

Fig. 15A

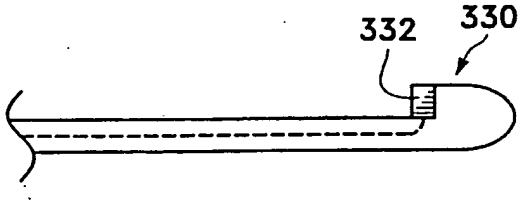

Fig. 15B

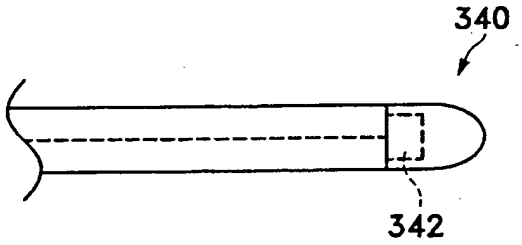

Fig. 16A

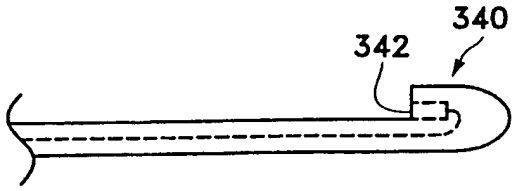

Fig. 16B

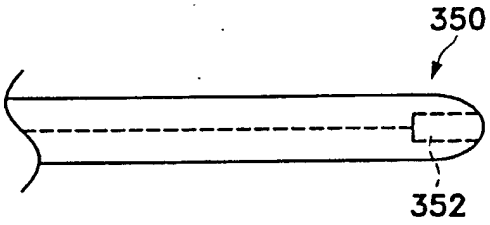

Fig. 17A

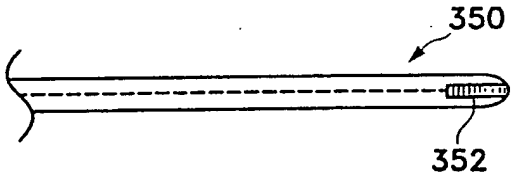

Fig. 17B

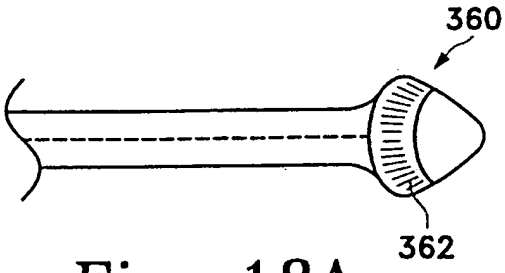

Fig. 18A

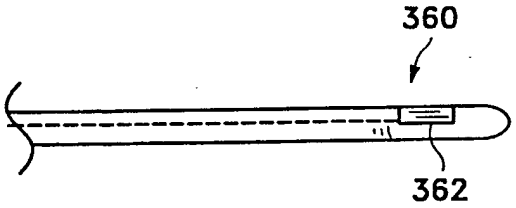

Fig. 18B

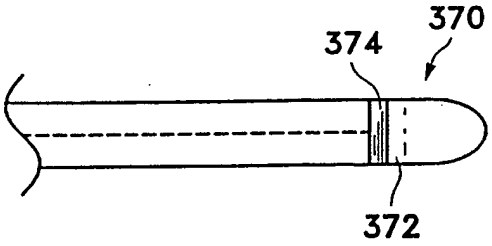

Fig. 19A

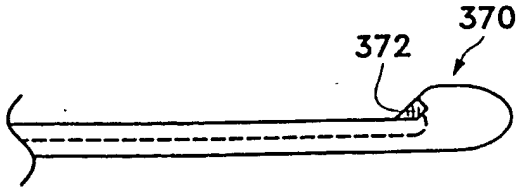

Fig. 19B

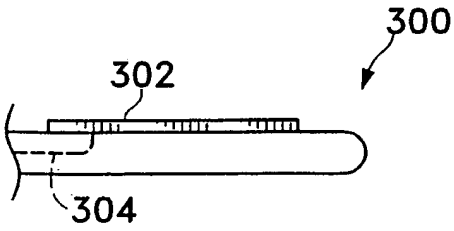

FIG. 12C

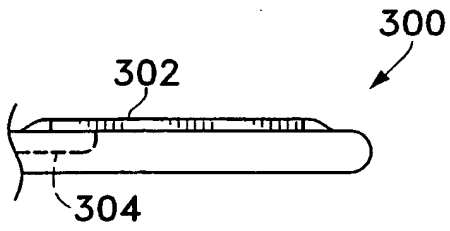

FIG. 12D

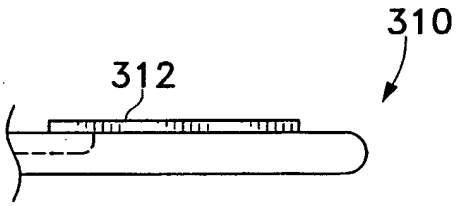

FIG. 13C

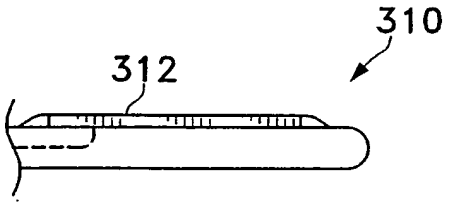

FIG. 13D

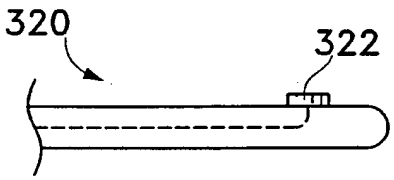

FIG. 14C

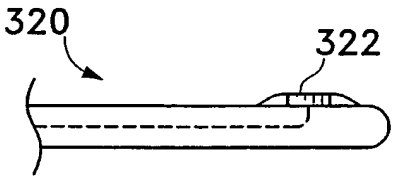

FIG. 14D

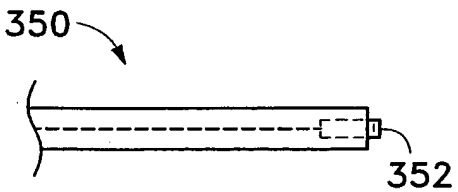

FIG. 17C

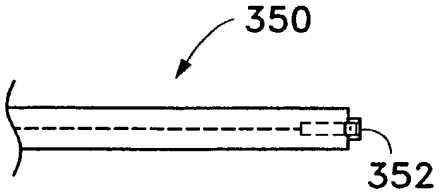

FIG. 17D

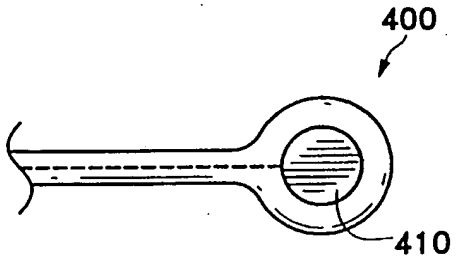

Fig. 20A

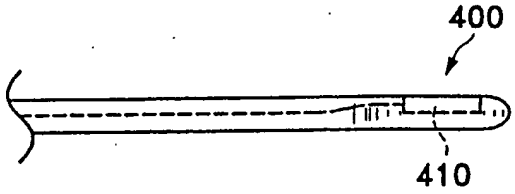

Fig. 20B

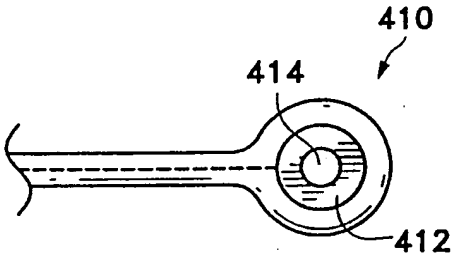

Fig. 21A

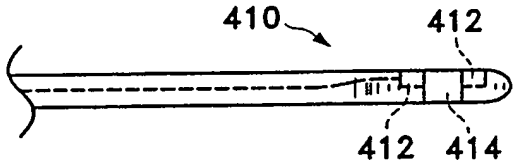

Fig. 21B

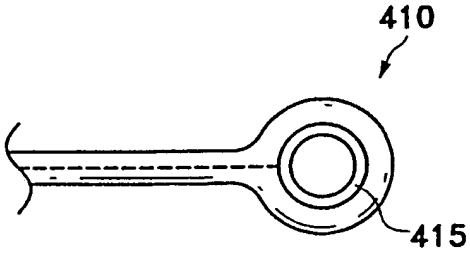

Fig. 21C

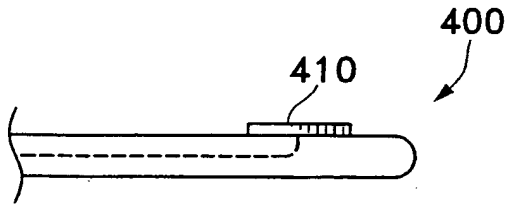

FIG. 20C

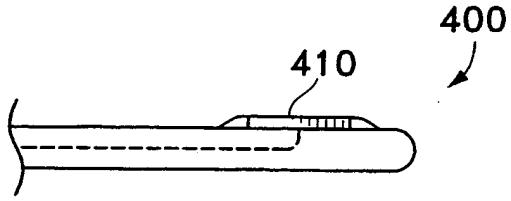

FIG. 20D

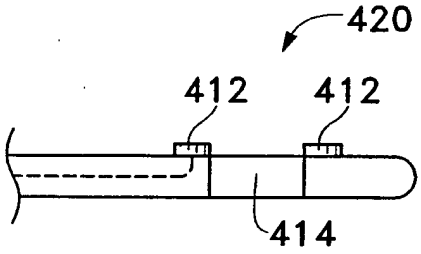

FIG. 21D

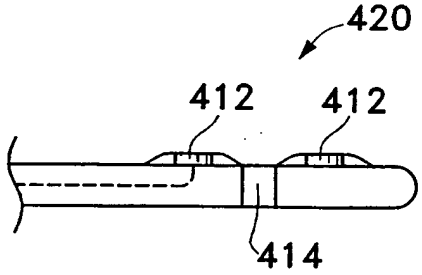

FIG. 21E

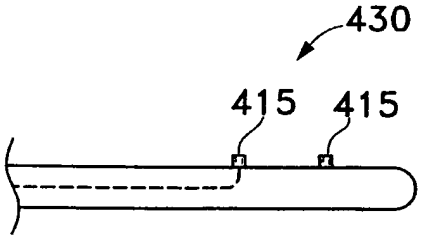

FIG. 21F

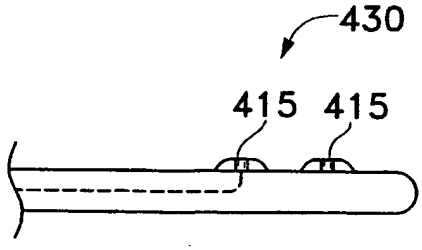

FIG. 21G

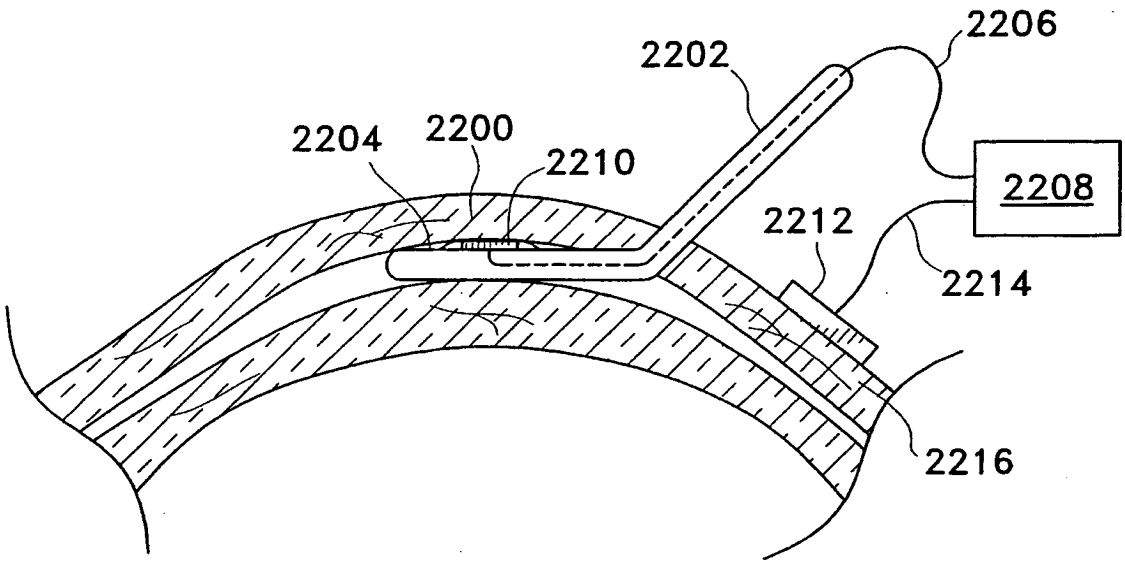

FIG. 22A

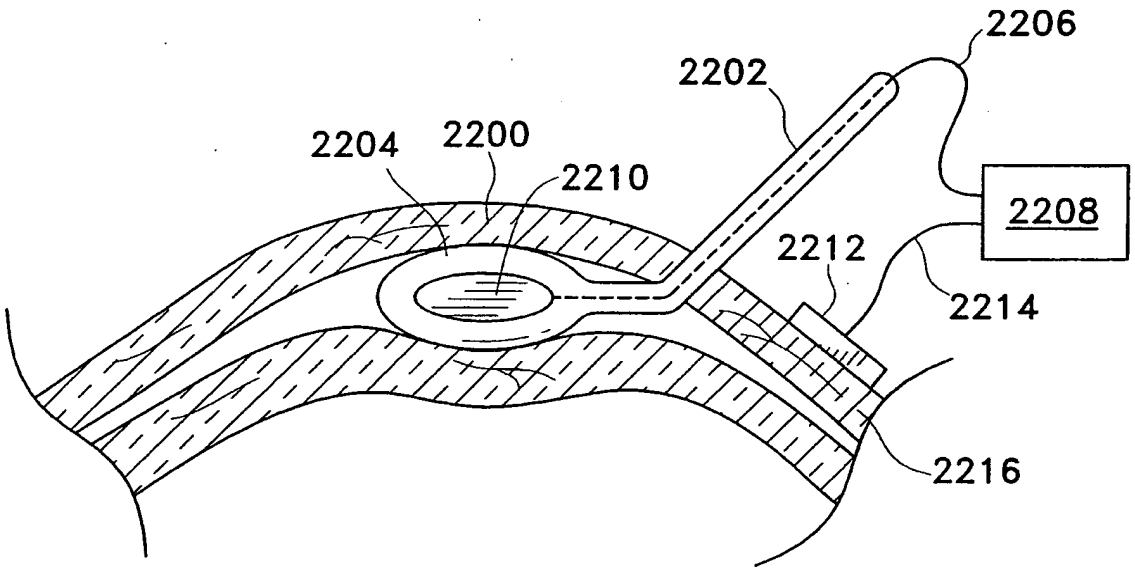

FIG. 22B

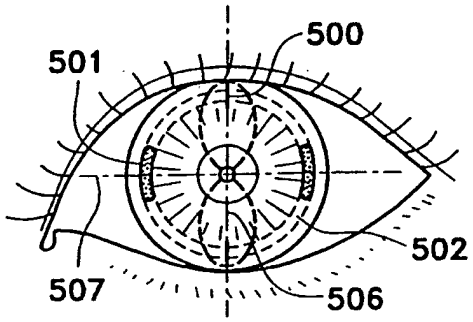

Fig. 23A

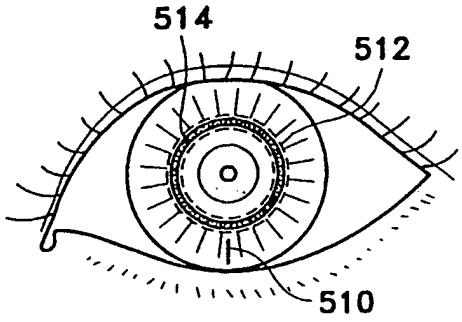

Fig. 23B

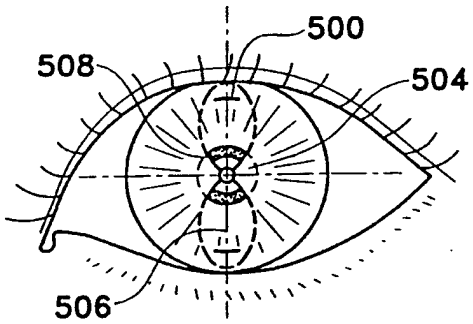

Fig. 23C

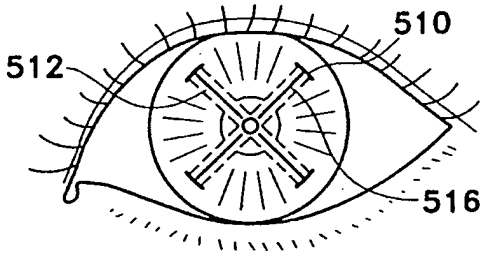

Fig. 23D

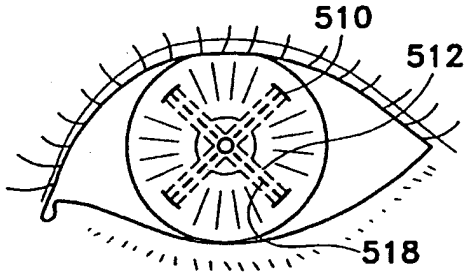

Fig. 23E

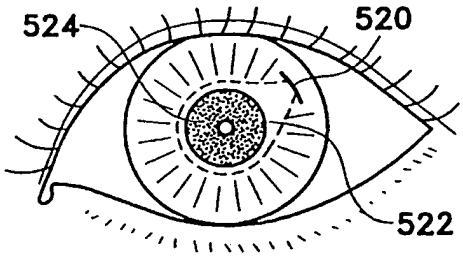

Fig. 23F

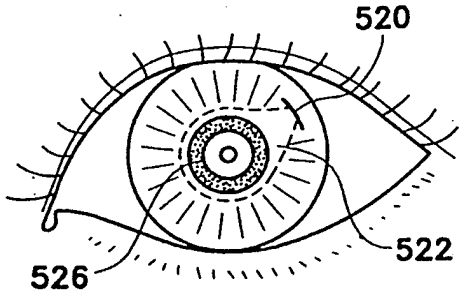

Fig. 23G

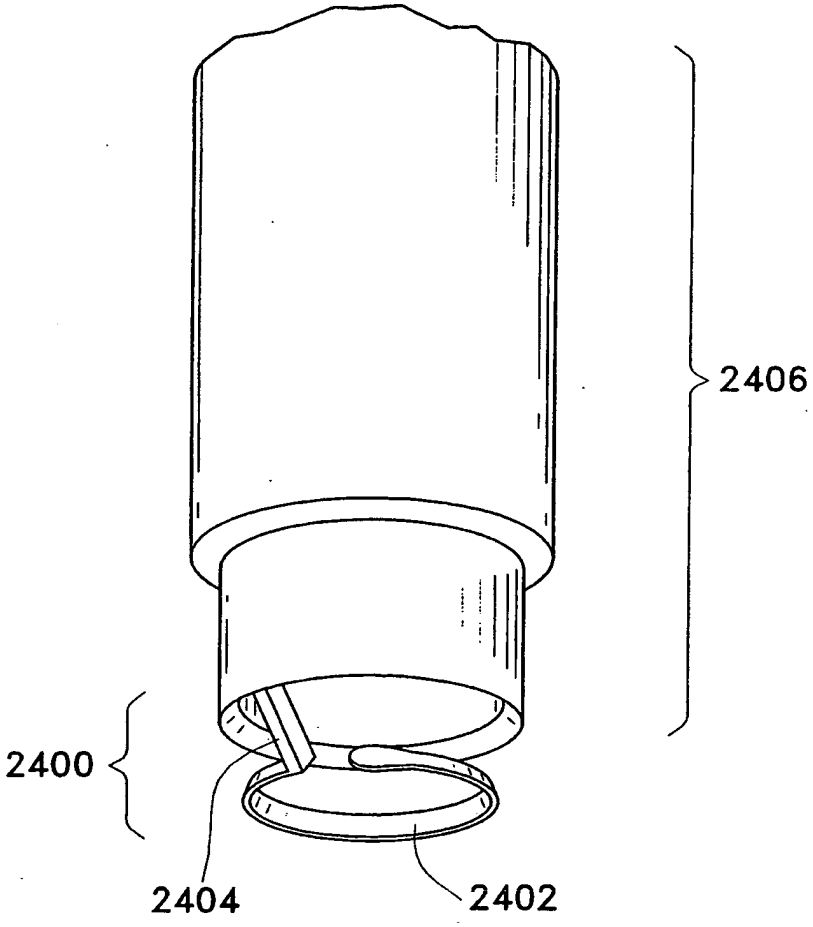

FIG. 24A

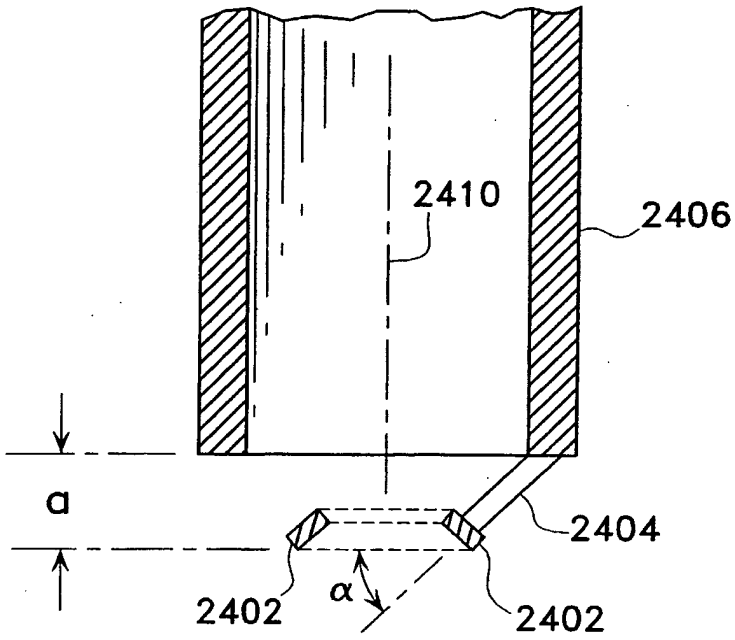

FIG. 24B

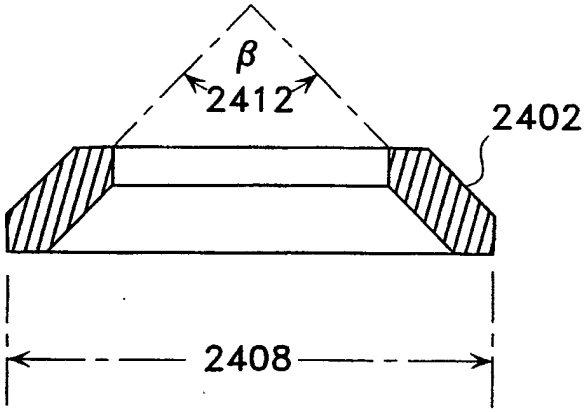

FIG. 24C

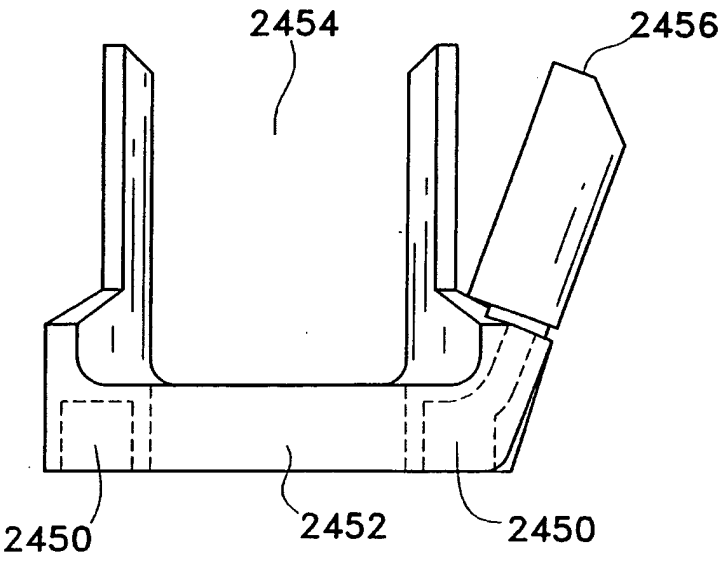

FIG. 24D

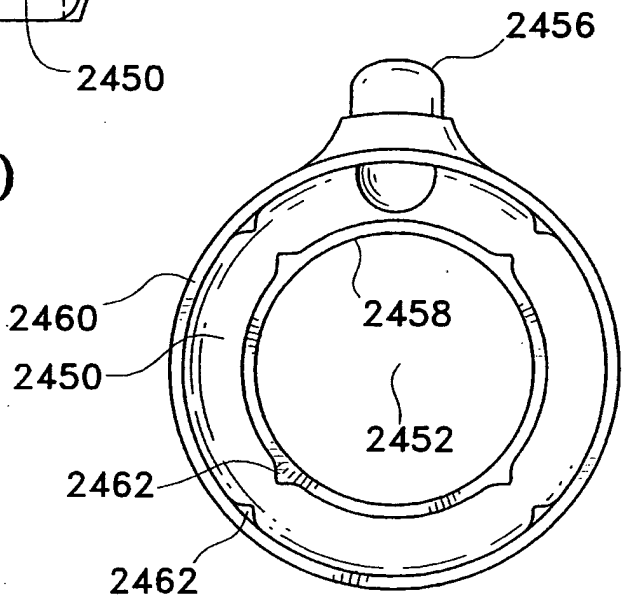

FIG. 24E

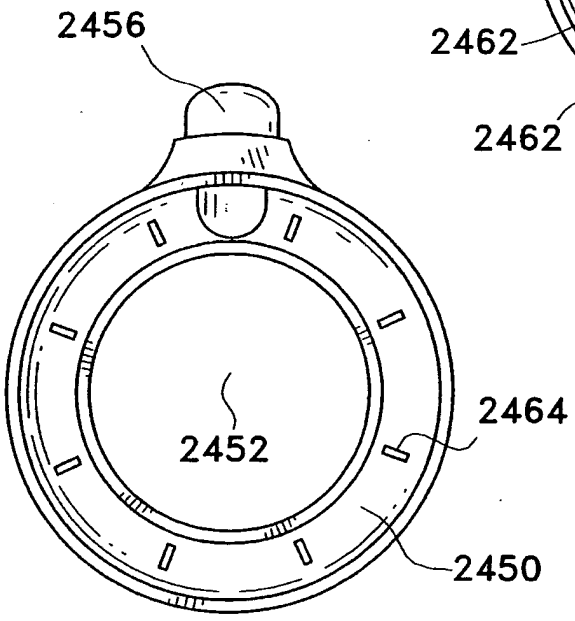

FIG. 24F

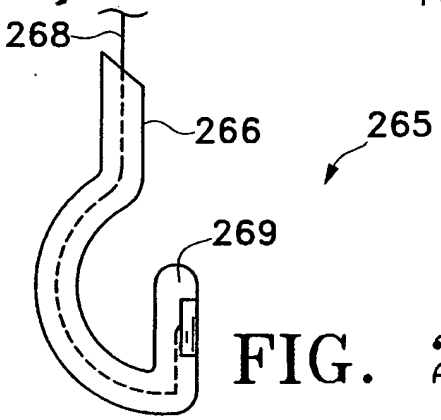

FIG. 25A

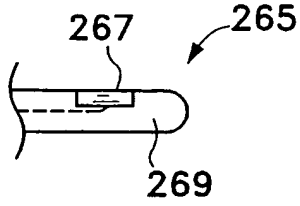

FIG. 25B

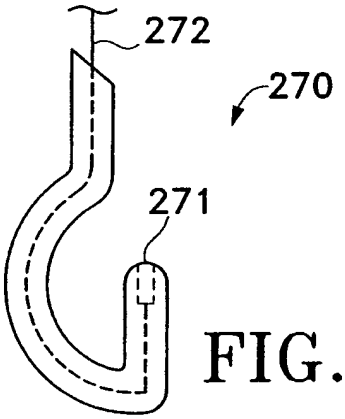

FIG. 26A

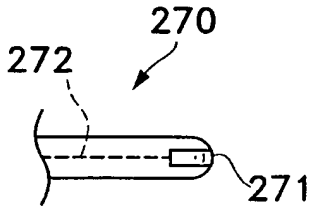

FIG. 26B

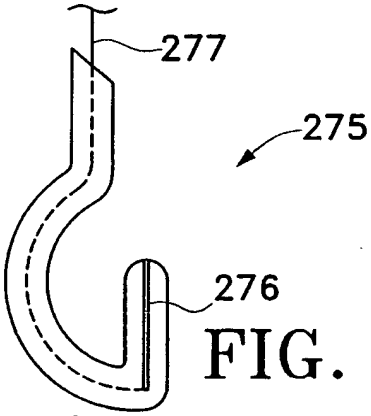

FIG. 27A

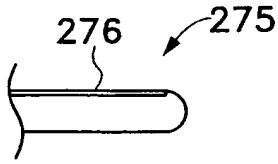

FIG. 27B

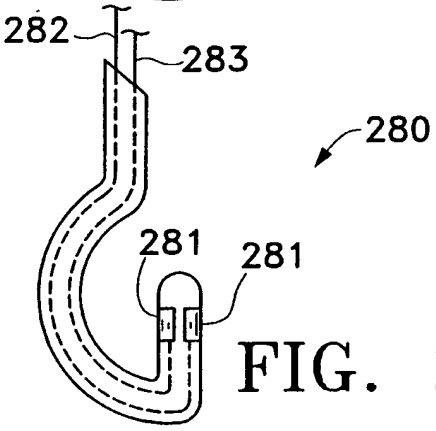

FIG. 28A

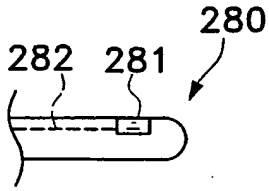

FIG. 28B

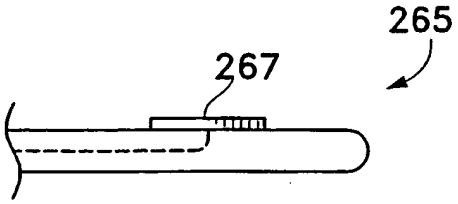

FIG. 25C

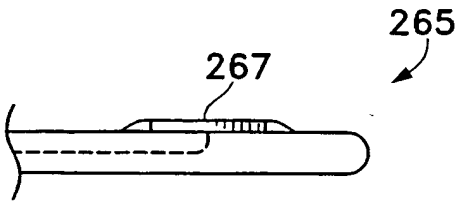

FIG. 25D

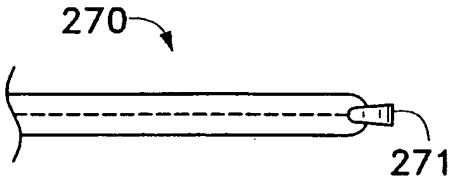

FIG. 26C

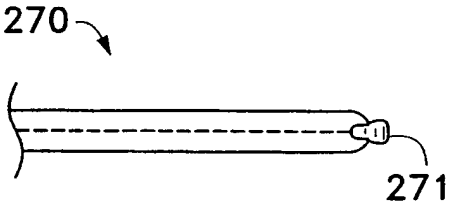

FIG. 26D

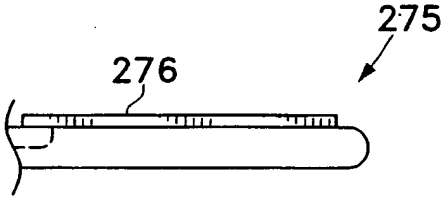

FIG. 27C

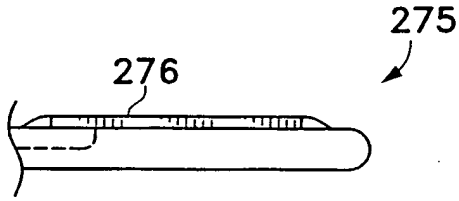

FIG. 27D

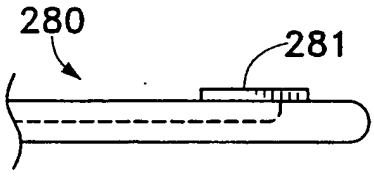

FIG. 28C

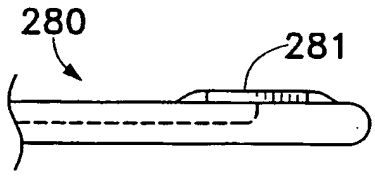

FIG. 28D

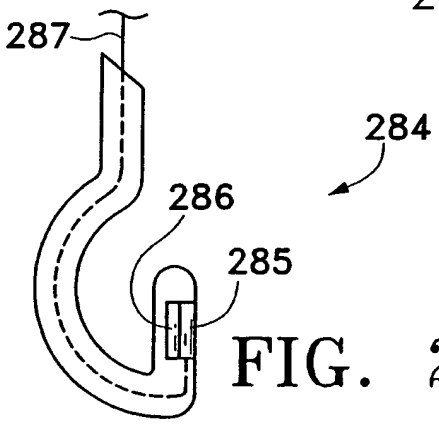

FIG. 29A

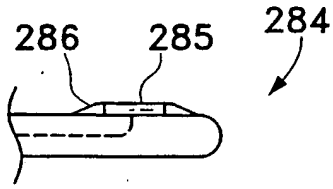

FIG. 29B

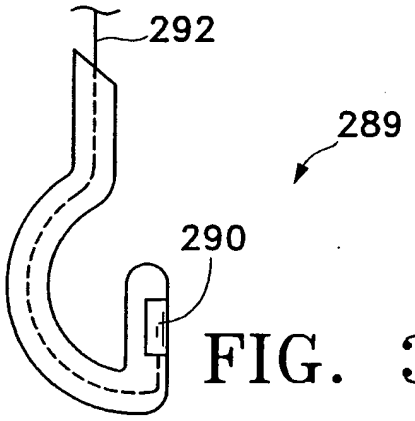

FIG. 30A

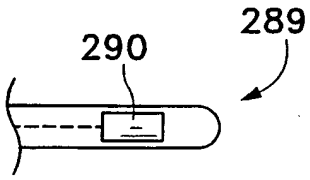

FIG. 30B

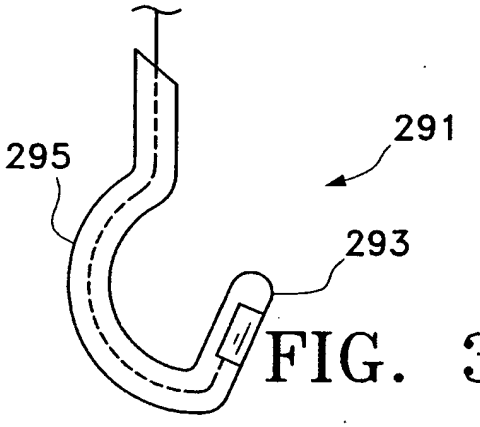

FIG. 31A

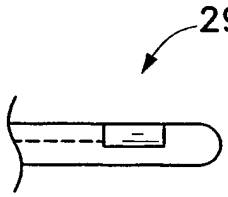

FIG. 31B

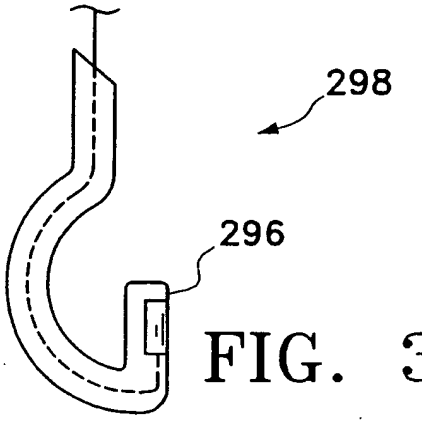

FIG. 32A

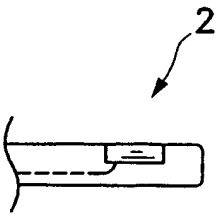

FIG. 32B

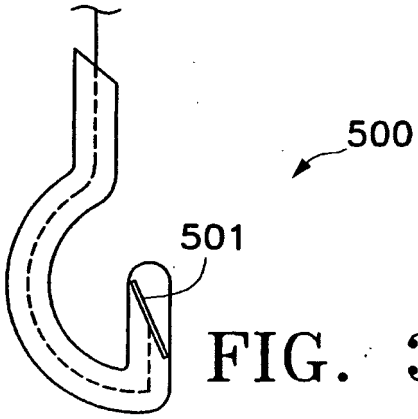

FIG. 33A

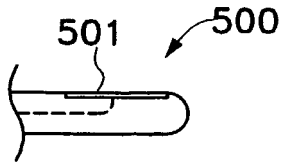

FIG. 33B

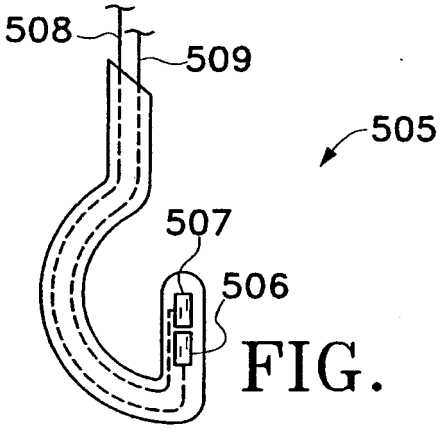

FIG. 34A

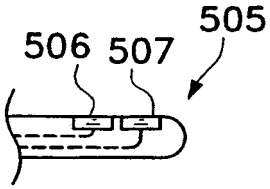

FIG. 34B

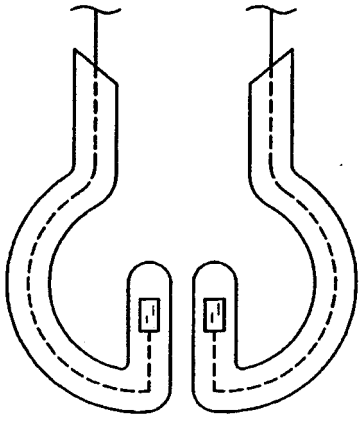

FIG. 35

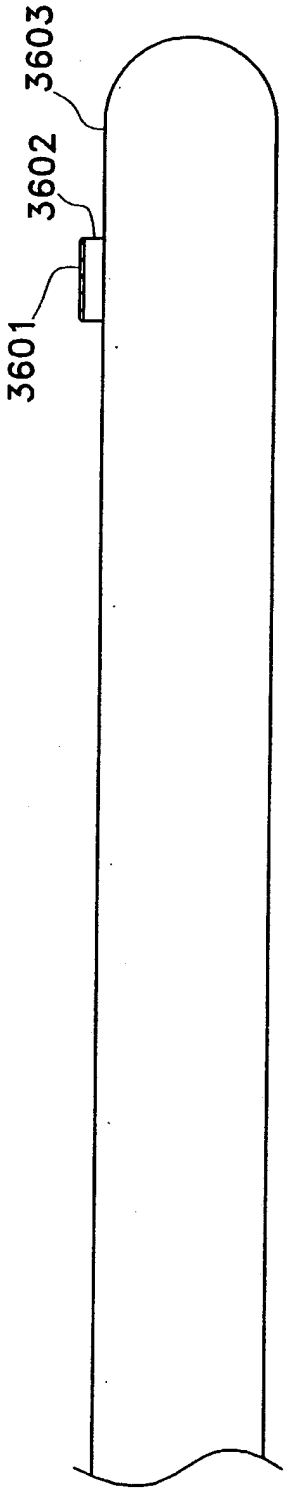

FIG. 36A

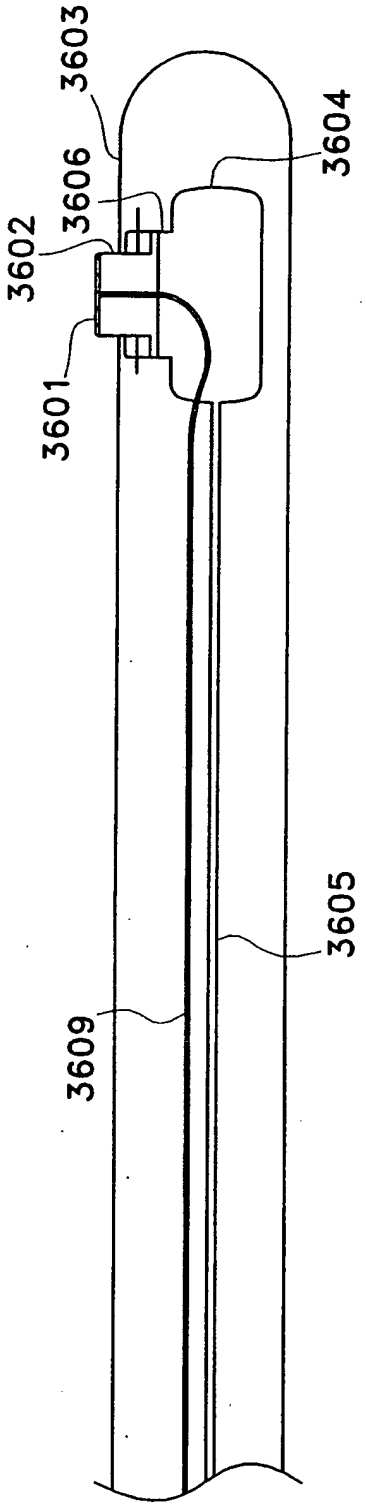

FIG. 36B

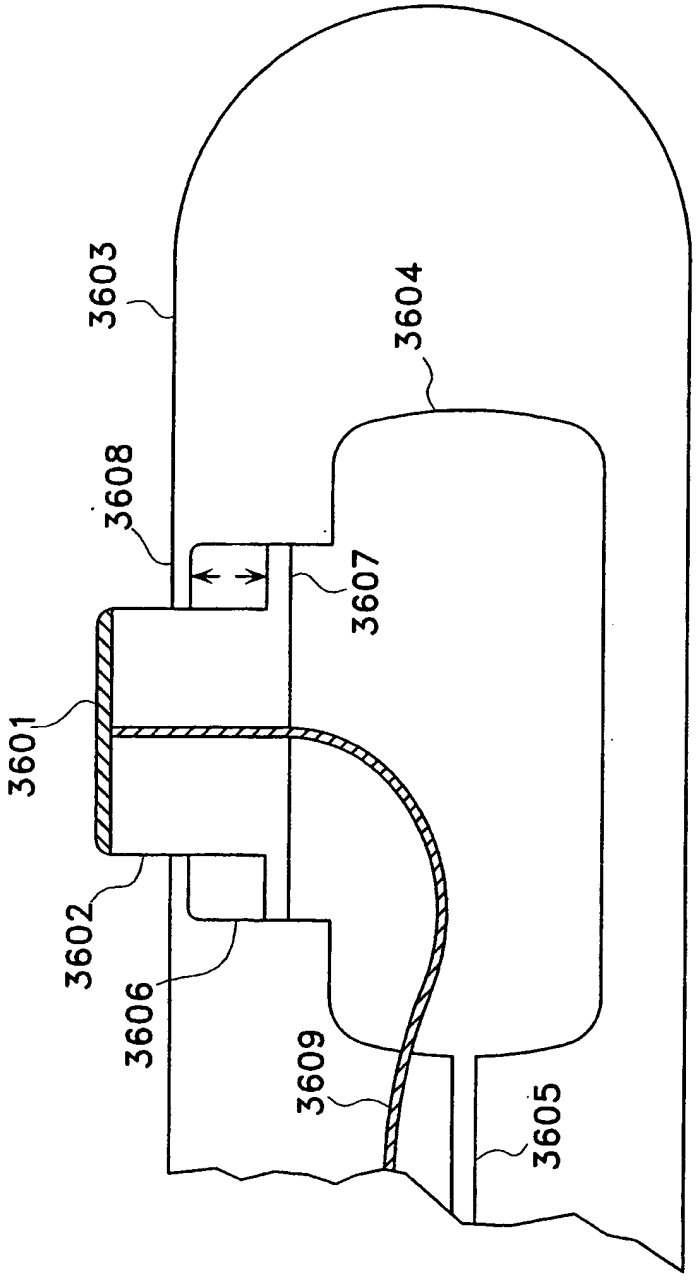

FIG. 36C

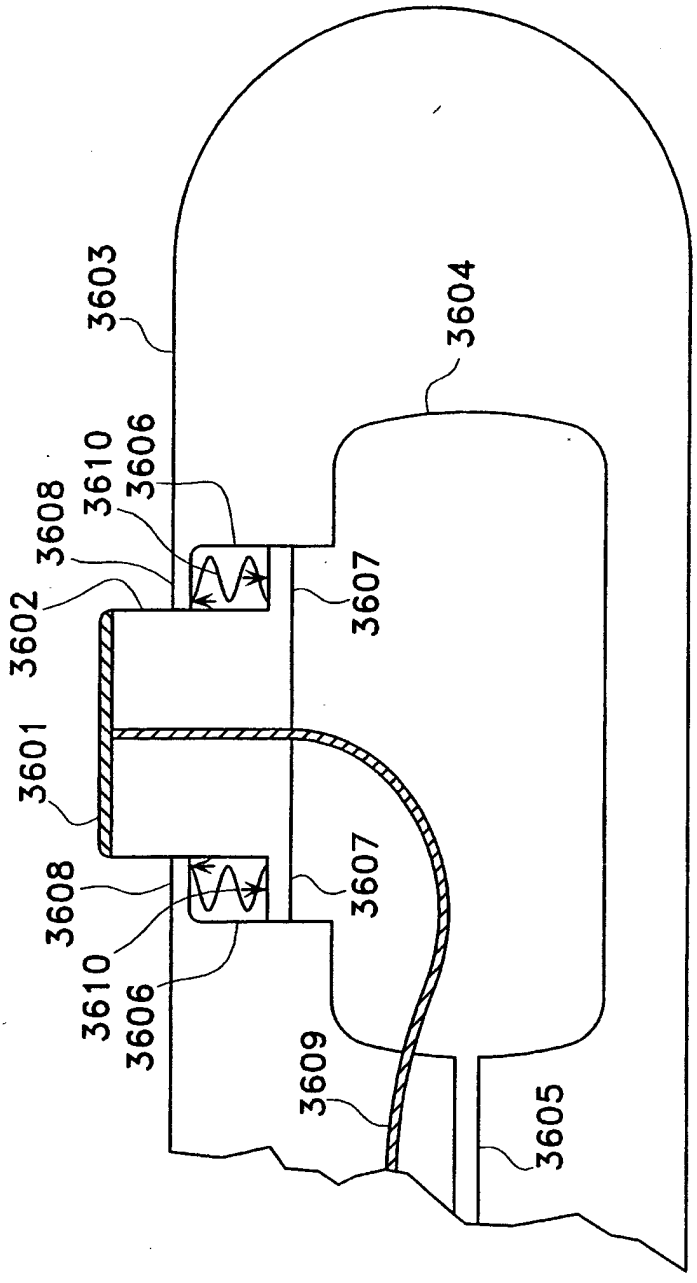
3603
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FIG. 36D

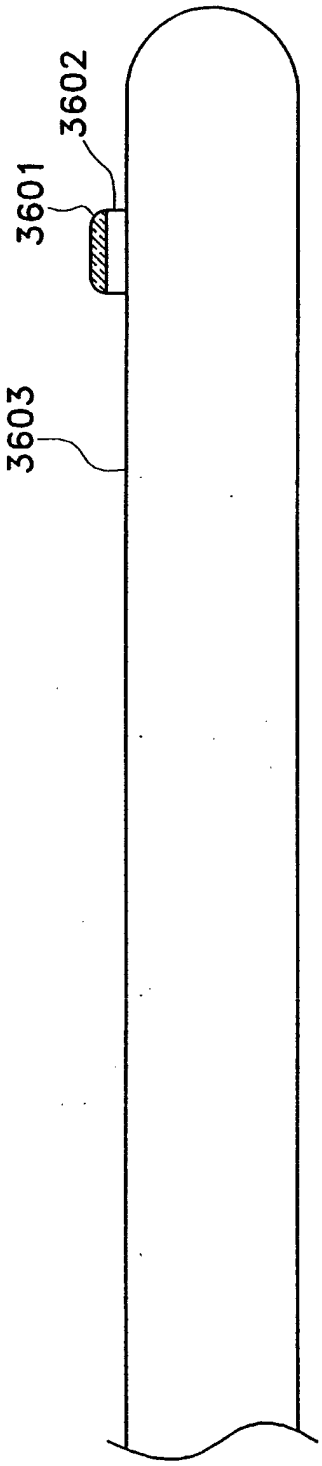
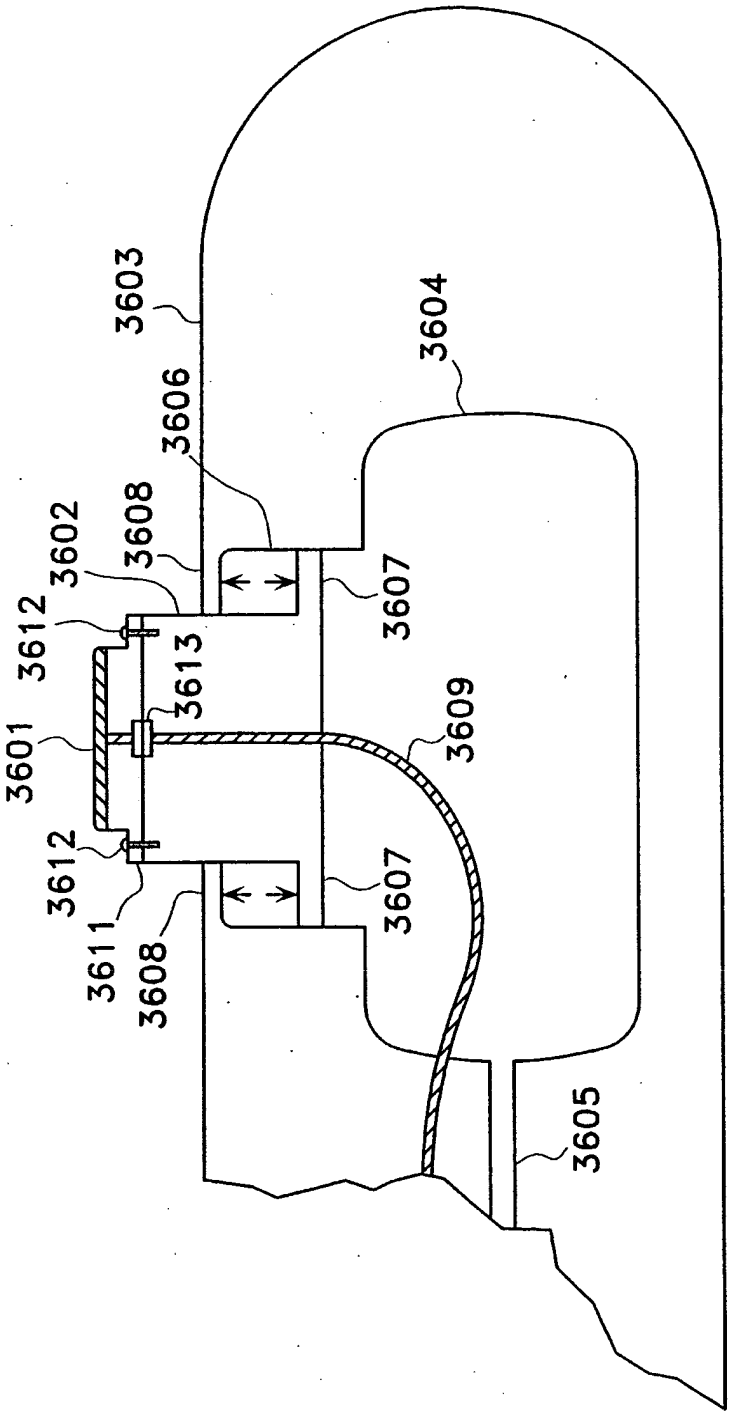


FIG. 36E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3605

FIG. 36F

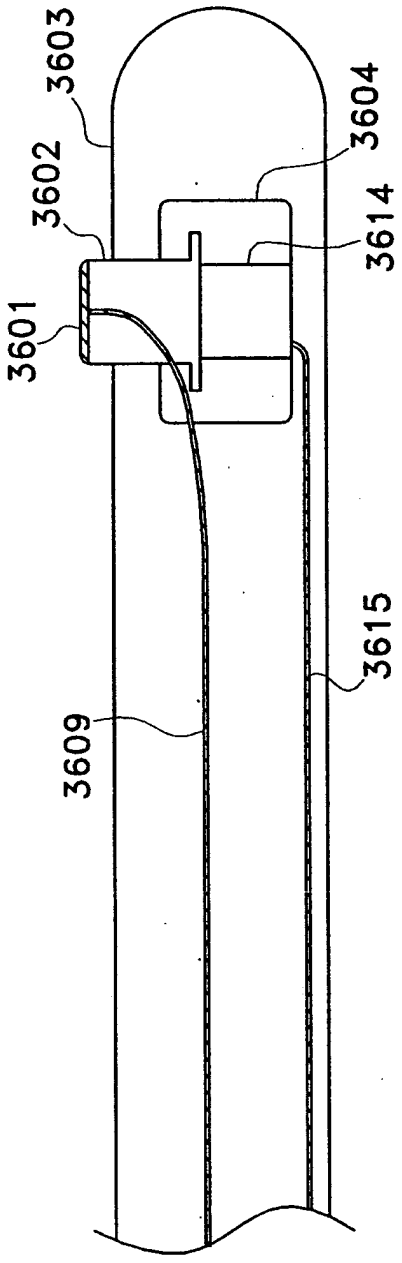

FIG. 36G

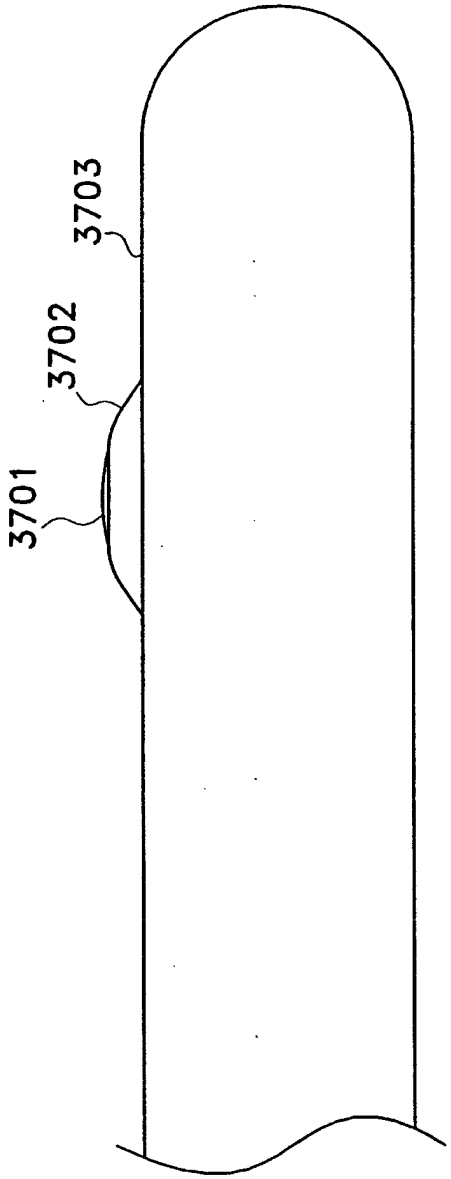

FIG. 37A

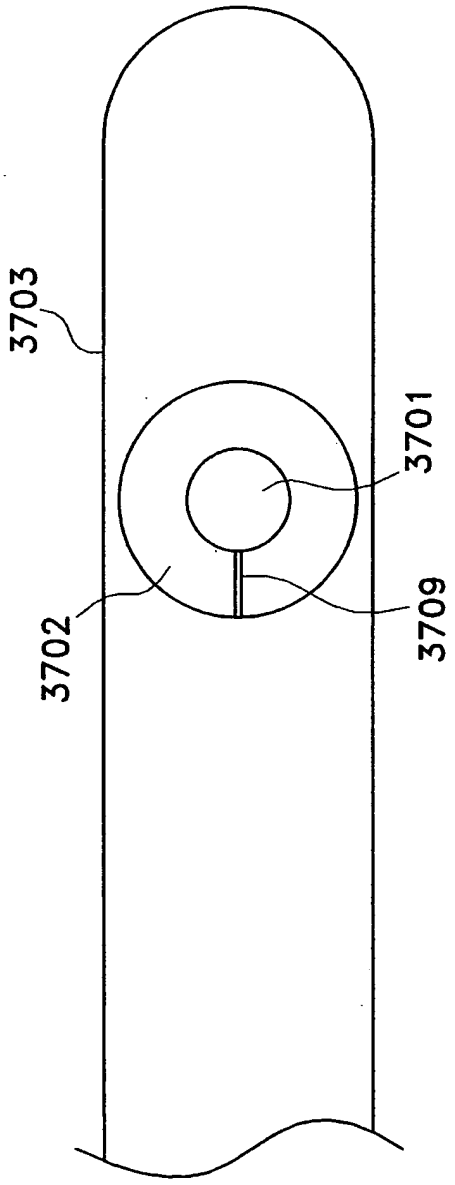

FIG. 37B

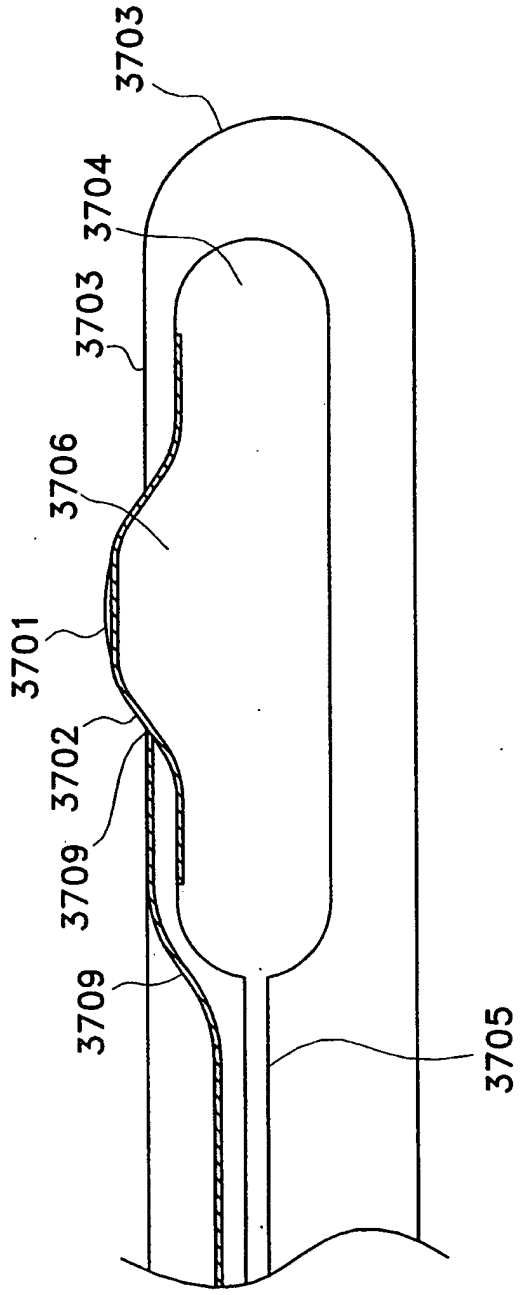

FIG. 37C

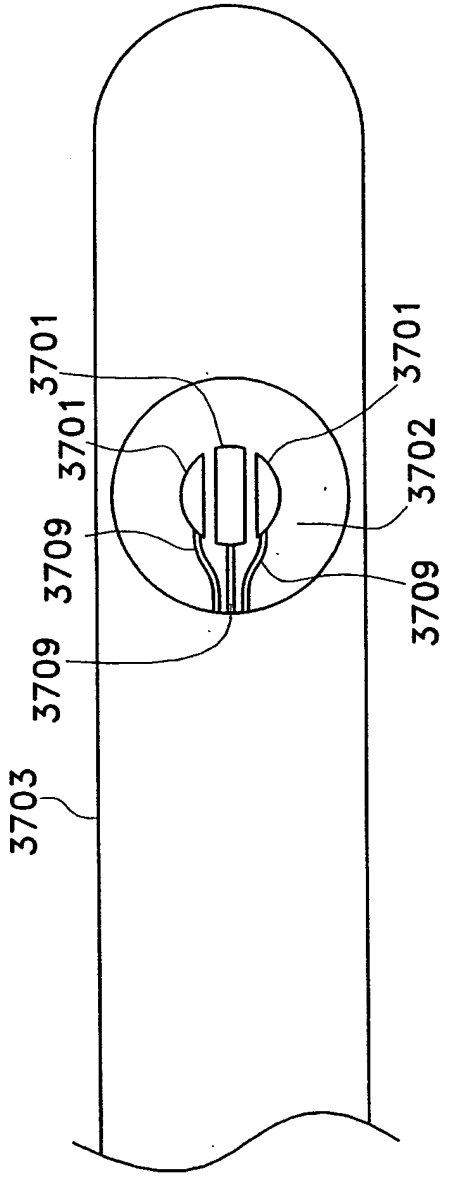

FIG. 37D

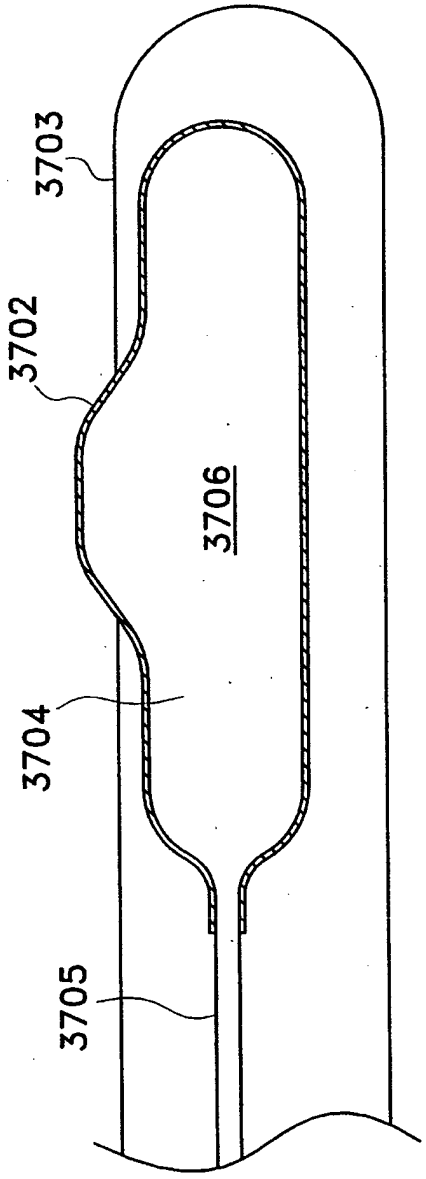

FIG. 37E

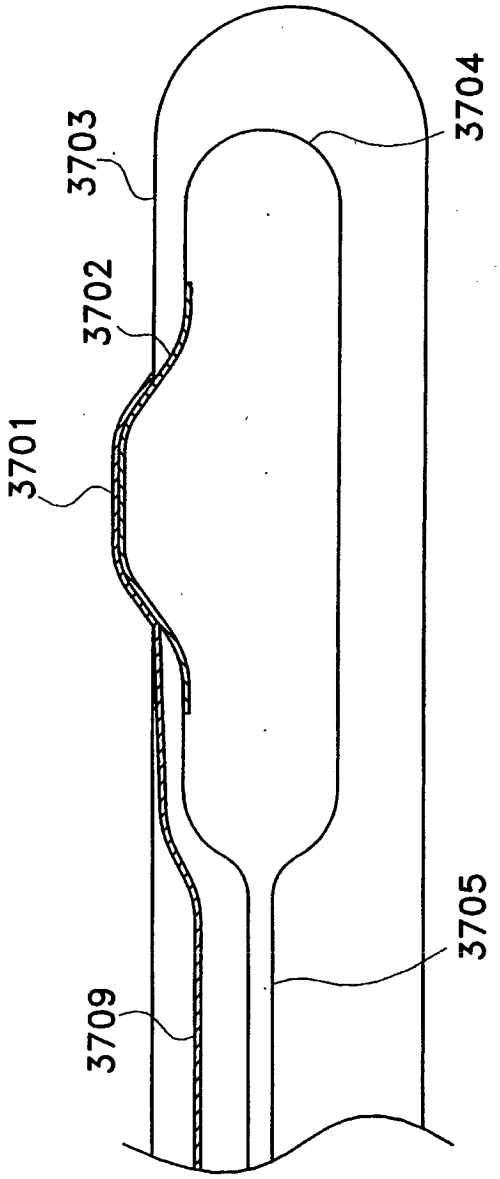

FIG. 37F

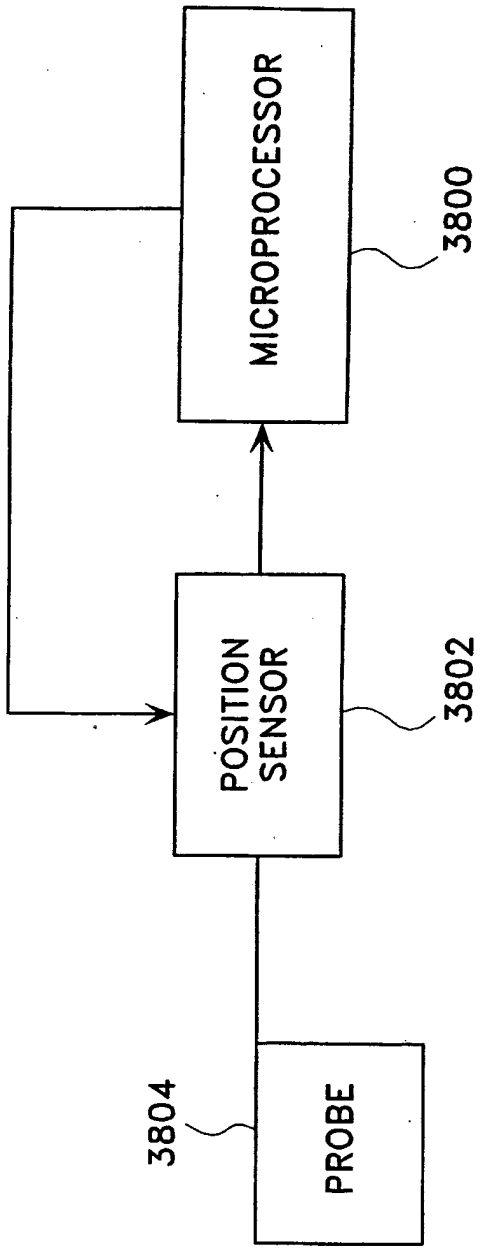

FIG. 38

INTERNATIONAL SEARCH REPORT

Interna il Application No
PCT/US 99/18519

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B18/14

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 4 326 529 A (DOSS JAMES D ET AL) 27 April 1982 (1982-04-27) column 3, line 39 - line 57; figure 2 ---	1,14,15, 17
A	WO 95 31142 A (APPLIED MED RESOURCES) 23 November 1995 (1995-11-23) page 15, line 34 -page 16, line 14; figure 1 ---	1-3,10, 11,14, 15,17
A	US 5 749 871 A (MENDEZ G ANTONIO ET AL) 12 May 1998 (1998-05-12) column 6, line 39 - line 61; figures 2,3,5 column 8, line 4 - line 18; figure 7 --- -/--	1,15,17

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
30 November 1999	07/12/1999

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Mayer, E

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 766 171 A (SILVESTRINI THOMAS A) 16 June 1998 (1998-06-16) column 7, line 58 -column 8, line 2; figure 3	1,17
A	EP 0 657 152 A (AMERICAN CYANAMID CO) 14 June 1995 (1995-06-14) column 8, line 48 - line 55; figure 3	1,17,18

INTERNATIONAL SEARCH REPORT

Inte ..ional application No.
PCT/US 99/ 18519

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 20-28
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1 (iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

Interna l Application No
PCT/US 99/18519

Patent document cited in search report		Publication date	Patent family member(s)		Publication date
US 4326529	A	27-04-1982	NONE		
WO 9531142	A	23-11-1995	US	5779698 A	14-07-1998
			EP	0760628 A	12-03-1997
			JP	10500333 T	13-01-1998
US 5749871	A	12-05-1998	AU	691198 B	14-05-1998
			AU	7601194 A	21-03-1995
			AU	8076998 A	08-10-1998
			BR	9407569 A	31-12-1996
			CA	2169943 A	02-03-1995
			EP	0715505 A	12-06-1996
			JP	9504447 T	06-05-1997
			NO	960716 A	22-04-1996
			PL	313222 A	10-06-1996
			WO	9505780 A	02-03-1995
			CN	1133001 A	09-10-1996
			US	5533999 A	09-07-1996
US 5766171	A	16-06-1998	AU	686743 B	12-02-1998
			AU	1700395 A	29-08-1995
			BR	9506762 A	07-10-1997
			CA	2183103 A	17-08-1995
			CN	1143900 A	26-02-1997
			EP	0743838 A	27-11-1996
			IL	112576 A	30-10-1998
			JP	9511161 T	11-11-1997
			SG	52621 A	28-09-1998
			WO	9521578 A	17-08-1995
EP 0657152	A	14-06-1995	US	5445636 A	29-08-1995
			US	5445637 A	29-08-1995
			AU	692799 B	18-06-1998
			AU	8023194 A	15-06-1995
			CA	2137211 A	07-06-1995
			JP	7250861 A	03-10-1995
			US	5885279 A	23-03-1999